

IHE International

Conformity Assessment Scheme

Part 2: Requirements for Conformity Assessment - 2016 Cycle
(IHE-CAS-2)
May 25, 2016

Approved by Conformity Assessment Coordination Committee on May 25th 2016



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1 Section 1 - General Information

1.1 Context

This document is the second of the two volumes of the IHE Conformity Assessment Scheme (IHE-CAS). It describes:

- The set of IHE profiles selected for IHE Conformity Testing by the 2015 and the 2016 Cycles.
- Test methods including: test cases, test tools and test data
- Templates to be used by test laboratories

IHE-CAS-2 builds upon the governance and processes of conformity assessment specified by IHE-CAS-1. See http://www.ihe.net/ Conformity_Assessment.aspx

IHE-CAS-2 provides requirements for assessing product conformance to the selected IHE Profiles. A Testing Report is delivered by an IHE Authorized Testing Laboratory as the result of this assessment.

IHE-CAS-2 also provides requirements for any Testing Laboratory in its accreditation and IHE authorization processes (see section 3.6 of IHE-CAS-1).

IHE-CAS-1 describes the governance and processes of conformity assessment including test laboratory accreditation and authorization processes (see section 3.6 of IHE-CAS-1).

1.2 Lifecycle

The IHE-CAS-2 document is periodically updated (typically every year) by the IHE International Conformity Assessment Coordination Committee (CAsC) as described in section 4.2 of IHE-CAS-1

The first version (2015 Cycle) of this document (July 2015) introduces an initial set of six Profiles that has been intentionally limited to enable the ramp-up of the IHE Conformity Assessment program by a limited number of IHE deployment Committees and IHE authorized laboratories.

The second version (2016 Cycle) of this document (May 2016) introduces an additional set of nine Profiles that now establishes the breadth of the IHE Conformity Assessment program by a number of IHE deployment Committees and IHE authorized laboratories.

The current version of this IHE-CAS-2 document is available at: See http://www.ihe.net/ Conformity_Assessment.aspx

1.3 Requirements for Test Labs and SUT in Using CAS-2

- 1.3.1 A testing laboratory offering conformity assessment of products shall select one or more Profiles listed in the table below. It shall offer conformity assessment of products for all Actors and profile-defined Option(s) listed in the table below.
- 1.3.2 A testing laboratory shall report in the detailed test report (using the template in Section 2.1.1) for the scope selected per Section 1.3.1, all performed test cases and their result: pass/fail/pass with comment. A testing Laboratory shall only include in the Summary Test Report the results for profile/actor/options for which the SUT passes or passes with comments the relevant test cases (See Section 3).
- 1.3.3 A party seeking conformity assessment of its product may select one or more Profiles listed below.



- 1.3.4 For each selected Profile, a party seeking conformity assessment may select one or more Actors among those listed in the table below.
- 1.3.5 For each Actor, a party seeking conformity assessment may select for testing the profile-defined Option(s) listed in the table below.

Table 1.3-1 Overview of the Profile/Actor pairs for which Conformity Assessment is available

| IHE Profile | Actors and Option (See sections 1.3.4 & 1.3.5) | Reference Technical Framework | Test Methods |
|--|---|--|------------------|
| | IT Infrastructure | 2 | |
| CT Consistent Time enables system clocks and time stamps of computers in a network to be synchronized (median error less than 1 second). | Time Client : - No Options | IHE IT Infrastructure Technical Framework Vol 1 – Section 7 | Section 3.1.1 |
| ATNA | Secure Application : | IHE IT Infrastructure | Section 3.2 |
| Audit Trail and Node Authentication | - No Option | Technical Framework : • Vol 1 – Section 9 | |
| Basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications. | | | |
| XDS.b Cross Enterprise Document Sharing | Document Registry: - Patient Identity Feed - Patient Identity Feed v3 | IHE IT Infrastructure Technical Framework: • Vol 1 – Section 10 | Section 3.3.4 |
| Share and discover electronic health record documents between healthcare enterprises, | Document Repository : - No Options | | Section 3.3.3 |
| physician offices, clinics, acute care in-patient facilities and personal health records. | Document Source : - Doc Replacement | | Section 3.3.2 |
| | Document Consumer : - No Options | | Section 3.3.1 |
| PDQ | Patient Demographics | IHE IT Infrastructure | Section |
| Patient Demographics HL7v2 | Consumer : - Pediatric Demographics | Technical Framework : • Vol 1 – Section 8 | 3.4.1 |
| Query a patient information server for a list of patients, based on user defined | Patient Demographics Supplier: - Pediatric | | Section 3.4.2 |



| IHE Profile | Actors and Option (See sections 1.3.4 & 1.3.5) | Reference Technical Framework | Test Methods |
|---|---|--|------------------|
| search criteria, and retrieve a patient's demographic information | Demographics | Demographics | |
| PDQv3 Patient Demographics Query HL7v3 | Patient Demographics Consumer: - Pediatric Demographics | IHE IT Infrastructure Technical Framework: • Vol 1 – Section 24 | Section 3.5.1 |
| Query a patient information server for a list of patients, based on user defined search criteria, and retrieve a patient's demographic information | Patient Demographics Supplier: - Pediatric Demographics | | Section 3.5.2 |
| PIXv3 Patient Identifier Cross Referencing HL7v3 | Patient Id Cross- Reference Consumer: - No Options | IHE IT Infrastructure Technical Framework: Vol 1 – Section 23 | Section 3.6.1 |
| Supports the cross- referencing of patient identifiers from multiple Patient Identifier Domains. | Patient Id Cross- reference Manager: - Pediatric Demographics | | Section 3.6.2 |
| PIX Patient Identifier Cross Referencing HL7v2 | Patient Id Cross- Reference Consumer: - No Options | IHE IT Infrastructure Technical Framework: • Vol 1 – Section 5 | Section 3.7.1 |
| Supports the cross- referencing of patient identifiers from multiple Patient Identifier Domains. | Patient Id Cross- reference Manager: - Pediatric Demographics | | Section 3.7.2 |
| PAM Patient Administration Management | Patient Demographic IHE IT Infrastructure | | Section 3.8.1 |
| Defines transactions based on message exchanges to support patient identity and encounter information, as well as movements within | Patient Demographic Supplier: - Merge - Link/Unlink | | Section 3.8.2 |
| an acute care encounter. | Patient Encounter Consumer: - Inpatient/ Outpatient - Maintain demographics - Advanced encounter management - Historic movement | | Section 3.8.3 |
| 1 | Patient Encounter | | Section |



| IHE Profile | Actors and Option (See sections 1.3.4 & | Reference Technical | Test |
|--|---|--|-------------------|
| | (See sections 1.3.4 & 1.3.5) | Framework | Methods |
| | Supplier: - Inpatient/ Outpatient - Maintain demographics - Advanced encounter management - Historic movement | | 3.8.4 |
| XCA | Initiating Gateway | IHE IT Infrastructure | Section 3.9.1 |
| Cross Community Access | - No Options | Technical Framework | |
| Supports the means to query and retrieve patient | | Vol 1 – Section 18 | |
| relevant medical data held by other communities. A community is defined as a coupling of facilities/ enterprises that have agreed to work together. | Responding Gateway - No Options | | Section 3.9.2 |
| XCPD | Initiating Gateway | IHE IT Infrastructure | Section |
| Cross Community Patient Discovery | - Deferred response | Technical Framework Vol 1 – Section 27 | 3.10.1 |
| Supports the means to locate communities that hold patient relevant health data and the translation of patient identifiers across communities holding the same patient's data. | Responding Gateway - No Options | | Section 3.10.1 |
| | Pathology and Laboratory | Medicine | |
| LAW Laboratory Analytical Workflow | Analyzer - No Options | PaLM Supplement – Laboratory Analytical Workflow (LAW) – Final Text 24 February 2016. | Section 3.11.1 |
| Supports the analytical workflow between analyzers (an IVD device) of the | | | |
| clinical laboratory and the systems managing their work such as a LAS or a LIS. Both patient and quality control (QC) specimens are in scope. | Analyzer Manager - No Options | | Section 3.11.2 |
| | Radiology | | 1 |
| XDS-I.b Cross-Enterprise Document | Imaging Document Consumer - No Options | IHE Radiology Technical Framework | Section 3.12.1 |



| IHE Profile | Actors and Option (See sections 1.3.4 & 1.3.5) | Reference Technical Framework | Test Methods |
|--|---|---|-------------------|
| Sharing for Imaging Supports the sharing (publishing, finding and retrieving) documents | Imaging Degument | Vol 1 – Section 18 | Section |
| across a group of affiliated enterprises. It extends and specializes the mechanisms defined by XDS.b to support imaging "documents" | Imaging Document Source - Set of DICOM Instances - PDF Report - CDA Wrapped Text Report - CDA Imaging Report with Structured Headings | | 3.12.2 |
| XCA-I Cross-Community Access for Imaging | Initiating Imaging Gateway - No Options | IHE Radiology Technical Framework Vol 1 – Section 29 | Section 3.13.1 |
| Supports query and retrieve patient-relevant medical imaging data being held by | | | |
| other communities It extends the IT Infrastructure XCA Profile by providing access to diagnostic reports, imaging Manifests and the imaging objects referenced in the Manifests. | Responding Imaging Gateway - No Options | | Section 3.13.2 |
| | Paztient Care Devi | ces | |
| Device Enterprise Communication Supports communication of vendor independent, multi- | Device Observation Consumer - No Options | IHE PCD Technical Framework Vol 1 – Section 3 | Section 3.14.1 |
| modality Patient Care Devices data to Enterprise Applications using consistent semantics. | Device Observation Reporter - No Options | | Section 3.14.2 |
| Point-of-care Infusion Verification Supports the electronic | Infusion Order Programmer - No Options | IHE PCD Technical Framework Vol 1 – Section 4 | Section 3.15.1 |
| transfer of infusion parameters from a Bedside Computer assisted | · | VOI I GGGGGT T | |
| Medication Administration (BCMA) system to a general-purpose infusion pump. This capability will reduce errors by eliminating | Infusion Order Consumer - No Options | | Section 3.15.2 |



| IHE Profile | Actors and Option (See sections 1.3.4 & 1.3.5) | Reference Technical Framework | Test Methods |
|--|--|----------------------------------|-----------------|
| keystroke errors and by increasing the use of automatic dosage checking and increase caregiver productivity. | | | |

1.4 Definitions

See IHE-CAS-1 Section 1.4 "Definitions". In addition, the following terms are defined.

Conformity

Conformity means compliance with standards, rules, or laws [NOAD]

Conformity Assessment

Testing to see if an implementation or product faithfully meets the requirements of a standard or specification. [ISO]

System Under Test (SUT)

A system implementation that has applied to be tested against a conformity assessment scheme.

Test Case

A set of test scripts including input values, execution preconditions, expected results and execution post-conditions, developed for a particular objective or test condition, such as to exercise a particular program path or to verify compliance with a specific requirement. [From IEEE 610]

Test Management Tool

A tool that provides support to the test management and controls part of a test process. It often has several capabilities, such as testware management, scheduling of tests, logging of results, progress tracking, incident management and test reporting.

Test Method

Defined technical procedure, test cases, test tools, test data and processes to determine one or more specified characteristics of a product.

Test Method Evaluation Report

A quality management report that covers the description of the test tools and test cases included, their requirements coverage, and the quality management process applied to the test tools development.

Testing Report

A document issued by an authorized and accredited testing laboratory, attesting to the performing of the test methods specified by the IHE conformity assessment scheme - Part 2 (CAS-2).



Test Scripts

Test procedures that describe the sequence of actions for the execution of a given test. (ISTQB)

Test Tool

A software that supports one or more test activities, such as planning and control, specification, building initial files and data, test execution and test analysis. [TMap].



2 Resources

2.1 Templates

Three templates are provided. Their names and relationship are shown in figure 2.1-1.

Summary Test
Report

Detailed
Test Report

Test Cases

Figure 2.1-1 Templates and Relationships

2.1.1 Test Case and Detailed Test Report Templates

The Test Case Template is included in Appendix A1. It is used by IHE-CAS to specify the test cases to be executed by Test Laboratories.

The Detailed Test Report Template is included in Appendix A2. It is used for reporting test execution by Test Laboratories. It builds upon the Test Cases template.

A Word file is available for users of these two templates such as an IHE International Authorized Testing Laboratory to report the execution of those test cases.



This template is use by the Test Cases listed in Section 3 to test a specific Profile/Actor. A Test Case includes one or more test scripts (Gazelle calls it a test) as well as the supporting test data.

An SUT (System under Test) plays one of the ROLES for which the test case has been specified. A ROLE is a list of Actor/Profile/Option combination to which a test case applies.

2.1.2 Templates used for summary reports of test execution

This Summary Report template is used by an IHE International Authorized Testing Laboratory to summarize the execution of test cases by a System Under Test per the principles stated in Section 1.3.2.. Such a summary is may be made publicly-available by IHE International or by the party seeking conformity assessment in promoting its conformity to specific IHE Profiles.

The Detailed Test Report Template is included in Appendix A3. A Word file is available to an IHE International Authorized Testing Laboratory to report the execution of test cases:





2.2 Types of test tools

IHE-CAS classifies the Interoperability Testing tools that support the execution of test cases in several categories (from EU Antilope Project D3.1 deliverable¹):

Test Management Tool: facilitates the execution of tests but may include additional functionalities that would be useful in performing the tests and collecting the results. This document will focus on two distinct groups within the wide range of Test Management tools:

- a) Tools that help organize and run large interoperability events involving large number of participants and a large number of tests. The tools in this group will typically manage test scenarios for peer-to-peer tests and may also support test planning and setup for large test events. They may also support the configuration process for all participating communication partners (e. g. IP addresses, ports, codes to be used, message types, other tools like simulators and validators). In order to trigger actual test runs, the software selects the communication partners from the pool of existing systems based on a number of criteria, including their communication capabilities and test instances required to reach the system's certification goals for the event (e. g. to run each test case with a certain number of distinct test partners). Such tools may also support other functionalities such as authoring of test cases and reporting of interim and final test results to the test managers and test partners.
- b) Execution frameworks that facilitate the selection of individual tests, collection of test results including evidence of tests performed such as pass/fail verdicts with corresponding traces.

Conformance testers: A conformance tester is an automated tool that is capable of checking the behaviour of the system under test. The tester takes the role of the communication partner, provides stimuli to the system under test, collects the responses and evaluates whether the order, timing and/or content of messages sent by the system under test conform to the requirements of a given standard and profile. Advanced testers may take the roles of all entities that are communicating with the system under test. In some situations a conformance tester is used to validate the structure and/or content of a document used in eHealth systems. Conformance tester tools vary in the extent to which they test the requirements in the profile. The simplest testers may only check some requirements, for example message or document syntax. Advanced conformance testing tool would check most or all important requirements. Depending on the level of precision in reporting problems discovered, conformance tester tools can provide valuable aid in rapid discovery and resolution of interoperability problems.

Interoperability Validator: automated tool that is checking the behavior of the system under test. It collects the messages exchanged between the two interacting systems one of which may be a simulator

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¹ Antilope: <u>www.antilope-project.eu</u>



tool and evaluates whether the order, timing and/or content of messages sent by the system under test conform to the requirements of a given standard and profile.

Interoperability validator tools vary considerably in their checking capabilities. Some may be dedicated to check only specific requirements, for example message or document syntax. In addition, the level of automation in triggering testing activities, in collecting the test traces and in the automated analysis of the test results can be quite different.

Simulator: is a tool acting as a connection partner to the system that needs to be tested.

In most cases, a simulator interacts with a system under test (SUT) in order to trigger certain behavior. For a system on a network, the simulator could send network messages. For other systems, it could simulate user input or any other input.

A simulator itself does not assess the behavior of the SUT. However, a simulator may have integrated capability to collect the trace of the exchange that could then be evaluated manually or using other means.

Simulator tools are useful for testing before peer-to-peer interoperability events or as replacement for needed communication partners that are not available.

Test data generator: accelerates test data preparation by providing valid, input data to be used in testing. The best results are achieved if a data generator can be used such that it efficiently generates data that both respects and exercises the constraints set by a profile being tested.

Support tools: During testing and debugging various support tools may be useful. While they do not test anything themselves, they may provide means of collecting the information that is needed to progress with testing. The examples are viewers that present the information in an understandable format, proxies that facilitate reliable and uniform collection of traces and many others.

Sniffers: also known as network analyzers or protocol analyzers. A sniffer is able to capture, record, decode and analyze communication protocol messages inside the data packages. This can be done transparently to the ongoing communication, as required by non-destructive protocol testing. Network sniffers must be able to decode all relevant communication protocols (TCP/IP, HL7, DICOM, etc.) in order to prepare message validation or other tasks. Sniffers are used not only in eHealth but are applicable to any domain that uses network messaging to exchange information.

2.3 Test tool requirements

Authors of Test Methods in Section 3 shall ensure that any test tools incorporated there comply with the following requirements and guidelines. The test tools:

- Shall have technical documentation, including the supporting operating system and development environment
- b) Shall either:
 - Be developed by organizations operating under ISO/IEC 17025 (or ISO/IEC 9001) quality system, or
 - Be validated by an IHE-designated organization under ISO/IEC 17025 (or ISO/IEC 9001) quality system
- c) Shall have an identified organization committed to maintaining the tool



- d) Shall have its source code available as open source (Apache or equivalent right to use and modify without having to contribute back changes)
- e) Shall have a proof for its validation (e.g. report per ISO/IEC 9001)
- f) Shall have demonstrated integration with a test management tool. For 2015 and 2016 Gazelle has been selected.
- g) Shall have a documented track record of use (e.g. used as part of pre-connectathon testing)
- h) Shall generate reports and documentation required for ISO/IEC 17025 (observer notes, check points, documentation templates) and enable efficient observer documentation generation
- i) Should be easy to install and use for the SUT and the testing monitor.
- j) Should be "extensible" to incorporate testing additional details for national extensions or other interoperability project specifications.

2.4 Test data requirements

Authors of Test Methods in Section 3 shall ensure that any test data incorporated there comply with the following requirements and guidelines. The test data:

- a) Should be dynamically generated or drawn from a large pool to prevent gaming of the system
- b) Should be clinically accurate (as vetted by clinicians)
- c) Shall contain data that is consistent within a test case and across test cases when relevant

2.5 Test Cases requirements

Authors of Test Cases in Section 3 shall ensure that the test Cases comply with the following requirements and guidelines. The test cases:

- a) Shall specifically address the "details" that formed the basis of including the Profile in CAS-2. (See Appendix A)
- b) Shall be efficient and pragmatic, meaning they:
 - Simplify test execution (e.g. do not repeat identical tests except in the case of test workflow and only when relevant)
 - Prioritize testing of sensitive areas
- c) Should be automated and easy to use for the SUT and the monitors.
- d) Shall calculate and document test coverage in terms of:
 - Number of requirements identified
 - Number of requirements addressed
 - % addressed (Number of requirements addressed/Number of requirements identified)
 - % not addressed (Number of requirements not addressed/ Number of requirements identified). Note: the two above should sum to 100%
- e) Shall include testing of responses to selected non-conforming exchanges



- f) Shall include testing of the breadth of the scope of the test cases
- g) Shall be placed under requirements traceability management (linked to the IHE Technical Framework)
- h) Shall either:
 - Be developed by organizations operating under ISO 17025 (or ISO 9001) quality system, or
 - Be validated by an IHE-designated organization under ISO 17025 (or ISO 9001) quality system
- i) Shall have a documented track record of use (e.g. used as part of pre-connectathon testing)



3 Test methods

The specification of the 2015 Cycle Test Methods are available on-line:

- Test Cases as a set of documents (based on the above template)
- Test Data as set of files
- Test Tools Including the IHE Gazelle test management tool (gazelle.ihe.net)

Each Test Case is identified by a name and an ID number.

A Test Case plus the associated Test Data also receives a unique "permanent reference number" plus a "time stamp". If corrections are applied either to the test case or to the test data or to both, the time stamp will change, but not the permanent number.

A System Under Test (SUT) shall be tested using the test methods as specified in this section (See IHE-CAS-1 Section 5.4.2). SUTs shall succeed at all test cases for the profile/actor pair and option(s) selected for Conformity Assessment.

Test Data to be used as part of the test methods specified in this Section 3, is specified by the Test Cases and is available along with the Test Tools. It is not intended to use alternative test data. This may be considered in future versions of CAS-2.

3.1 Profile CT

The Consistent Time Profile enables system clocks and time stamps of computers in a network to be synchronized (median error less than 1 second).

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:7, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case pass with a comment.

3.1.1 Time Client Actor

3.1.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data Version and Reference | Supporting Test Tool ID |
|---------------------|------------------------------------|---|--|----------------------------|
| CT_Client_ Synch | CT Time Synchroniza tion NTP | CT Client Synchronizes with Time Server | Version: CATS2015 Last Modified: 3/26/15 5:50:04 PM Permanent number: 12558 | None |



3.1.1.2 List of related test tools

Not applicable.

3.2 Profile ATNA

The Consistent Time Profile enables Basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:9, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case pass with a comment.

3.2.1 Secure Application Actor

3.2.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data Version and Reference | Supporting Test Tool ID |
|---|---|--|---|----------------------------|
| ATNA_Co mplete_Que stionnaire | ATNA: Complete Questionnair e | ATNA: Complete Questionnaire | Version: CATS2016 Last Modified: 3/30/16 2:28:05 PM Permanent number: 12553 | Gazelle Security Suite |
| ATNA_Me ssage_Send | ATNA: Send messages to Audit Record Repository | The purpose of this test is to check that your system correctly implements the syslog protocol | Version: CATS2015 Last Modified: 4/21/15 4:22:01 PM Permanent number: 12562 | Syslog collector |
| ATNA_Au dit_message _check | ATNA - Audit message check | Audit message check | Version: CATS2016 Last Modified: 3/30/16 2:45:05 PM Permanent number: 12556 | Gazelle Security Suite |
| ATNA_Aut hentication_ Test | ATNA - Authenticati on test | Test authentication using TLS and certificates | Version: CATS2016 Last Modified: 3/30/16 2:32:50 PM Permanent number: 12554 | Gazelle Security Suite |
| ATNA_Aut hentication_ Error_Cases | ATNA - Authenticati on error cases | Test TLS authentication error cases | Version: CATS2016 Last Modified: 3/30/16 2:43:06 PM Permanent number: 12564 | Gazelle Security Suite |



3.2.1.2 List of related test tools

| Test Tool ID | Name | Version | Developed by | Info Page | Category |
|--|--|------------|-----------------|--|-----------|
| Syslog Collector | Simulator for collecting syslog messages | 2.1 | MIR | http://ihewiki.wustl.ed u/wiki/index.php/Syslo g Message Browser | Simulator |
| Gazelle Security SuiteSecur ity Suite | PKI, TLS Simulator and ATNA Questionna ire | 5.2.05.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.3 Profile XDS.b

The Cross-Enterprise Document Sharing Profile enables sharing and discovery of electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:10, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case pass with a comment.

3.3.1 Document Consumer Actor

One option may be selected by the SUT:

- Doc Replacement

3.3.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|----------------------------------|--|--|--|----------------------------|
| XDS.b_CO NS_Configu ration | XDS.b registry and repository configuratio n for Document Consumer | Description of the configuration of the registry and repository used for testing | Version: CATS2015 Last Modified: 4/8/16 4:54:42 PM Permanent number: 12517 | XDS Toolkit |



| XDS.b_CO NS_Query | XDS.b Consumer testing | A list of steps to be executed to verify the consumer is able to interact with a registry/repository | Version: CATS2015 Last Modified: 4/16/15:3:04:34 PM Permanent number: 12518 | XDS Toolkit |
|---------------------------------|---|---|--|-------------|
| XDS.b_CO NS_Retriev e_TLS | XDS.b Document Consumer Retrieve over TLS | The Document Consumer retrieves successfully a binary document from the document Repository, over TLS transaction | Version: CATS2015 Last Modified: 4/16/15 3:03:59 PM Permanent number: 12519 | XDS Toolkit |

3.3.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Develop ed by | Test Tool Info Page | Tool Category |
|--|---|-------------------------|------------------|-------------------------|-----------------------|
| XDSToolki t | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulator & Validator |
| Gazelle Security SuiteSecu rity Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05. 2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.3.2 Document Source Actor

3.3.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------------|---|---|--|----------------------------|
| XDS.b_SR C_Replace | XDS.b Document Source - Replace Existing Document | Verify that Document Source can issue a document replacement | Version: CATS2015 Last Modified: 4/17/15 2:44:41 PM Permanent number: 12552 | XDS Toolkit |
| XDS.b_SR C_Submit | Submit one document via XDS.b | Verify that the XDS.b Document Source can submit a single document via Provide and Register Document Set-b transaction. | Version: CATS2015 Last Modified: 4/17/15 4:31:35 PM Permanent number: 12542 | XDS Toolkit |

3.3.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|-----------------|----------------|-------------------------|-----------------|-------------------------|--------------------------|
| XDSToolkit | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulator & Validator |



| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---|--|-------------------------|-----------------|-------------------------|---------------|
| Gazelle Security SuiteSecurity Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05.2. 0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.3.3 Document Repository Actor

3.3.3.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|--|---|----------------------------|
| XDS.b_REP _PnR | XDS.b - Document Repository - Accept one document via XDS.b | Verify that the XDS.b Document Repository can accept a single document via the Provide and Register Document Set-b transaction and forward the updated metadata to the Public Registry. | Version: CATS2015 Last Modified: 4/16/15 3:38:31 PM Permanent number: 12543 | XDS Toolkit |
| XDS.b_REP _PnR_TLS | XDS.b - Document Repository - Accept one document via XDS.b over TLS | Verify that the XDS.b Document Repository can accept a single document via the Provide and Register Document Set-b transaction and forward the updated metadata to the Public Registry. Transaction over TLS | Version: CATS2015 Last Modified: 4/16/15 3:22:54 PM Permanent number: 12544 | XDS Toolkit |
| XDS.b_REP _PnR_XDS RepositoryE rr | XDS.b - Document Repository - XDSRepository MetadataError | Testing the XDSRepositoryMetadataError Error as applied to supplied size and hash attributes. | Version: CATS2015 Last Modified: 4/16/15 3:38:43 PM Permanent number: 12545 | XDS Toolkit |
| XDS.b_REP _RegErrors | XDS.b - Document Repository - Return Errors from Registry (XDS.b) | Return Errors from Registry (XDS.b) | Version: CATS2015 Last Modified: 4/16/15 3:27:51 PM Permanent number: 12546 | XDS Toolkit |
| XDS.b_REP _Retrieve | XDS.b - Document Repository - Retrieve Document Set | Accept Retrieve Document Set – two documents | Version: CATS2015 Last Modified: 4/16/15 3:28:35 PM Permanent number: 12547 | XDS Toolkit |
| XDS.b_REP _Retrieve_S ingle_Doc | XDS.b - Document Repository - Retrieve single Document | Accept Retrieve Document Set – single document | Version: CATS2015 Last Modified: 4/16/15 3:29:01 PM Permanent number: 12548 | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------------------|---|---|---|----------------------------|
| XDS.b_REP _Retrieve_T LS | XDS.b - Document Repository - Retrieve Document Set over TLS | Accept Retrieve Document Set – single document via TLS | Version: CATS2015 Last Modified: 4/16/15 3:29:43 PM Permanent number: 12549 | XDS Toolkit |
| XDS.b_REP _Submit2 | XDS.b - Document Repository - Submit Two Document | Verify that the XDS.b Document Repository can accept a submission containing two documents | Version: CATS2015 Last Modified: 4/16/15 3:38:57 PM Permanent number: 12550 | XDS Toolkit |
| XDS.b_REP _Submit_Re ject | XDS.b - Document Repository - Reject submissions | Reject submissions where metadata and documents do not match (XDS.b) | Version: CATS2015 Last Modified: 4/16/15 3:39:08 PM Permanent number: 12551 | XDS Toolkit |

3.3.3.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|--|---|-------------------------|-----------------|-------------------------|--------------------------|
| XDSToolkit | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulator & Validator |
| Gazelle Security SuiteGazelle Security Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.3.4 Document Registry Actor

Two options may be selected by the SUT:

- Patient Identity Feed
- Patient Identity Feed v3

3.3.4.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------------------|---|---|---|----------------------------|
| XDS.b_RE G_Associati on | XDS.b - Document Registry - Association Documentation Classifications | Test the Registry actors management of a Association Documentation Classifications | Version: CATS2015 Last Modified: 4/16/15 3:03:30 PM Permanent number: 12520 | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|----------------------------------|---|--|---|----------------------------|
| XDS.b_RE G_Configur ation | Load test data into Document Registry via Register.b transaction | Load test data into Document Registry via Register.b transaction | Version: CATS2015 Last Modified: 4/16/15 3:05:20 PM Permanent number: 12521 | XDS Toolkit |
| XDS.b_RE G_Folder_2 | XDS.b - Document Registry - Accept Create Folder with Initial Document | Verify that the XDS.b Document Registry can accept the submission of a Folder with a document. | Version: CATS2015 Last Modified: 4/16/15 3:06:05 PM Permanent number: 12522 | XDS Toolkit |
| XDS.b_RE G_Folder_3 | XDS.b - Document Registry - Accept Add New Document to Folder | Verify that the XDS.b Document Registry can accept a submission that contains a document which is added to an existing folder. | Version: CATS2015 Last Modified: 4/16/15 3:06:40 PM Permanent number: 12523 | XDS Toolkit |
| XDS.b_RE G_Folder_4 | XDS.b - Document Registry - Reject Add Document to Folder | Verify that the XDS.b Document Registry will reject a submission that contains a document which is added to an existing folder with a different Patient ID | Version: CATS2015 Last Modified: 4/16/15 3:07:25 PM Permanent number: 12524 | XDS Toolkit |
| XDS.b_RE G_Folder_A dd | XDS.b - Document Registry - Add Existing document to existing folder | Add Existing document to existing folder | Version: CATS2015 Last Modified: 4/16/15 3:35:37 PM Permanent number: 12525 | XDS Toolkit |
| XDS.b_RE G_Folder_R epl | XDS.b - Document Registry - R.b Accept Document Replace, Document in Folder | Accept Document Replace, Document in Folder | Version: CATS2015 Last Modified: 4/16/15 3:35:53 PM Permanent number: 12526 | XDS Toolkit |
| XDS.b_RE G_lastUpdat eTime | XDS.b - Document Registry - Folder lastUpdateTime | Test an XDS.b Document Registry implementation to prove it can properly manage the XDSFolder.lastUpdateTime attribute | Version: CATS2015 Last Modified: 4/16/15 3:09:02 PM Permanent number: 12527 | XDS Toolkit |
| XDS.b_RE G_R.b_TLS | XDS.b Document Registry Register Document Set Single Document over TLS | Test the Document Registry regarding the transaction Register Document Set - Submistion of single document over TLS | Version: CATS2015 Last Modified: 4/16/15 3:36:18 PM Permanent number: 12528 | XDS Toolkit |
| XDS.b_RE G_R.b_Tran s_RPLC | XDS.b Document Registry Register Document Set - Transform/Replace | Test the Document Registry regarding the transaction Register Document Set - Transform/Replace documents | Version: CATS2015 Last Modified: 4/16/15 3:36:33 PM Permanent number: 12529 | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|--|---|----------------------------|
| XDS.b_RE G_R.b_Unk nownPatient Id | XDS.b Document Registry Register Document Set - Invalid Patient ID | Test the Document Registry regarding the transaction Register Document Set - Reject Submission of Invalid Patient ID via XDS.b | Version: CATS2015 Last Modified: 4/16/15 3:36:52 PM Permanent number: 12530 | XDS Toolkit |
| XDS.b_RE G_R.b_XD SPatientIdD oesNo | XDS.b Document Registry Register Document Set - Patient ID does not match Document | Test the Document Registry regarding the transaction Register Document Set - Reject Submission Set, Patient ID does not match Document (XDS.b) | Version: CATS2015 Last Modified: 5/27/15 5:38:59 PM Permanent number: 12531 | XDS Toolkit |
| XDS.b_RE G_Register_ Create_Fold er | XDS.b Document Registry Register Document Set - Create Folder | Test the Document Registry regarding the transaction Register Document Set - Accept Create Folder | Version: CATS2015 Last Modified: 4/16/15 3:37:15 PM Permanent number: 12532 | XDS Toolkit |
| XDS.b_RE G_Register_ Query_Add enda | XDS.b Document Registry Register Document Set - Document Addendum | Test the Document Registry regarding the transaction Register Document Set - Document Addendum | Version: CATS2015 Last Modified: 4/16/15 3:37:26 PM Permanent number: 12533 | XDS Toolkit |
| XDS.b_RE G_Register_ Query_Mult ipl | XDS.b Document Registry Register Document Set - Multiple Document | Test the Document Registry regarding the transaction Register Document Set - Submistion of multiple documents | Version: CATS2015 Last Modified: 4/16/15 3:37:40 PM Permanent number: 12534 | XDS Toolkit |
| XDS.b_RE G_Register_ Query_Repl ace | XDS.b Document Registry Register Document Set - Replace Document | Test the Document Registry regarding the transaction Register Document Set - replace document | Version: CATS2015 Last Modified: 4/16/15 3:37:55 PM Permanent number: 12535 | XDS Toolkit |
| XDS.b_RE G_Register_ Query_Singl e | XDS.b Document Registry Register Document Set Single Document | Test the Document Registry regarding the transaction Register Document Set - Submistion of single document | Version: CATS2015 Last Modified: 4/16/15 3:38:07 PM Permanent number: 12536 | XDS Toolkit |
| XDS.b_RE G_Register_ Query_Tran for | XDS.b Document Registry Register Document Set - Document Transform | Test the Document Registry regarding the transaction Register Document Set - Document Transform | Version: CATS2015 Last Modified: 4/16/15 3:16:45 PM Permanent number: 12537 | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|---|--|---|----------------------------|
| XDS.b_RE G_Resubmi ssion | XDS.b - Document Registry - R.b Document Resubmission | Verify that the XDS.b Document Registry will accept a duplicate XDSDocumentEntry, with same DSDocumentEntry.uniqueId, if XDSDocumentEntry.hash is the same reject if the hash is different | Version: CATS2015 Last Modified: 4/16/15 3:17:09 PM Permanent number: 12538 | XDS Toolkit |
| XDS.b_RE G_RollBack | XDS.b - Document Registry - Submission Stored - All or Nothing | Verify the capability of Document Registry to rollback a complete submission | Version: CATS2015 Last Modified: 4/16/15 3:17:35 PM Permanent number: 12539 | XDS Toolkit |
| XDS.b_RE G_Stored_Q uery | XDS.b Stored Query Testing | Test the ability of document registry to respond to SQ transaction | Version: CATS2015 Last Modified: 4/16/15 3:18:45 PM Permanent number: 12540 | XDS Toolkit |
| XDS.b_RE G_XDSRes ultNotSingl ePati | XDS.b - Document Registry - XDSResultNotSing lePatient Error | Testing the XDSResultNotSinglePatient Error. | Version: CATS2015 Last Modified: 4/16/15 3:20:10 PM Permanent number: 12541 | XDS Toolkit |

3.3.4.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---|--|-------------------------|-----------------|-------------------------|--------------------------|
| XDSToolkit | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulator & Validator |
| Gazelle Security SuiteSecurity Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05.2. 0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.4 Profile PDQ

The Patient Demographics Query Profile enables the query of a patient information server for a list of patients, based on user defined search criteria, and retrieve a patient's demographic information.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:8, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:



- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.4.1 Patient Demographic Consumer Actor

One option may be selected by the SUT:

- Pediatric Demographics

3.4.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------------------------|---|---|--|---|
| PDQ_PDC_P ediatricDemo graphics | PDQ/PDC Query with Pedriatric Demographics | This test evaluates the capability of the SUT to support the Pediatric Demographics Option | Version: CATS2015 Last Modified: 03/24/15 21:30:42 Permanent number: 12485 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDC_ Query | PDQ/PDC Query with various parameters | This test evaluates the capability of the SUT to send a valid query to the PatientManager tool acting as a PDQ supplier | Version: CATS2015 Last Modified: 04/15/15 13:32:57 Permanent number: 12481 | Gazelle Patient Manager GazelleHL7Vali dator |

3.4.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Develope d by | Test Tool Info Page | Tool Categor y |
|---|---|-------------------------|------------------|-------------------------|----------------------|
| Gazelle PatientManager | Patient Manager | 9.2.29.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Val idator | HL7 V2 and V3 Message Validator | 3.2.13.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security SuiteSecurity Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.4.2 Patient Demographic Supplier Actor

One option may be selected by the SUT:

- Pediatric Demographics

3.4.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
|-----------------|-------------------|-----------------------|---|----------------------------|



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------------------------|--|---|--|---|
| PDQ_PDS_ Case1 | PDQ/PDS Case 1: Data Found - Single Domain | This test checks the ability of your system to answer to an exact match query in a single domain | Version: CATS2015 Last Modified: 02/04/15 15:43:14 Permanent number: 12486 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDS_ Case2 | PDQ/PDS Case 2: Data Found - Single Domain | This test checks the ability of your system to answer to a query in a single domain | Version: CATS2015 Last Modified: 02/04/15 15:43:31 Permanent number: 12487 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDS_ Case3 | PDQ/PDS Case 3: Unknown Domain | This test checks the ability of your system to answer to a query with an unknown value in QPD-8 | Version: CATS2015 Last Modified: 02/04/15 15:43:48 Permanent number: 12488 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDS_ Continuatio n_Pointer | PDQ/PDS Continuation Pointer | This test checks the ability of your system to support the HL7 Query Continuation Pointer Protocol | Version: CATS2015 Last Modified: 24/03/15 21:18:52 Permanent number: 12489 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDS_ PediatricDe mographics | PDQ/PDS Pediatric Demographics option | This test checks the ability of your system to support the pediatric demographics option | Version: CATS2015 Last Modified: 02/04/15 15:44:07 Permanent number: 12490 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQ_PDS_ Prerequisite | PDQ/PDS Pre- Requisite | This test explains how to configure both your System and the tooling to perform the following test cases in the best conditions | Version: CATS2015 Last Modified: 02/04/15 11:35:07 Permanent number: 12491 | Gazelle Patient Manager GazelleHL7Vali dator |

3.4.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---|--|----------------------|-----------------|-------------------------|------------------|
| Gazelle PatientManager | Patient Manager | 9.2.29.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Vali dator | HL7 V2 and V3 Message Validator | 3.2.13.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security SuiteSecurity Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.05.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |



3.5 Profile PDQ-V3

The Patient Demographics Query-V3 Profile enables the query of a patient information server for a list of patients, based on user defined search criteria, and retrieve a patient's demographic information.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:24, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.5.1 Patient Demographic Consumer Actor

One option may be selected by the SUT:

- Pediatric Demographics

3.5.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---|---|---|---|---|
| PDQV3_PD C_Pediatric Demographi cs | PDQV3/PDC Query with Pedriatric Demographics | This test evaluates the capability of the SUT to support the Pediatric Demographics Option | Version: CATS2015 Last Modified: 3/24/15 4:15:45 PM Permanent number: 12496 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQV3_PD C_Query | PDQV3/PDC Query with various parameters | This test evaluates the capability of the SUT to send a valid query to the PatientManager tool acting as a PDQV3 supplier | Version: CATS2015 Last Modified: 4/2/15 11:19:23 AM Permanent number: 12492 | Gazelle Patient Manager GazelleHL7Vali dator |

3.5.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---------------------------|--|----------------------|-----------------|-------------------------|------------------|
| PatientManager | Patient Manager | 9.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Vali dator | HL7 V2 and V3 Message Validator | 3.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |



3.5.2 Patient Demographic Supplier Actor

One option may be selected by the SUT:

- Pediatric Demographics

3.5.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---|---|---|---|---|
| PDQV3_PD S_Case1 | PDQV3/PDS Case 1: Data Found - Single Domain | This test checks the ability of your system to answer to an exact match query in a single domain | Version: CATS2015 Last Modified: 4/2/15 3:44:26 PM Permanent number: 12497 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQV3_PD S_Case2 | PDQV3/PDS Case 2: Data Found - Single Domain | This test checks the ability of your system to answer to a query in a single domain | Version: CATS2015 Last Modified: 4/2/15 3:44:39 PM Permanent number: 12498 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQV3_PD S_Case3 | PDQV3/PDS Case 3: Unknown Domain | This test checks the ability of your system to answer to a query with an unknown value in otherIDsScopingOrganization | Version: CATS2015 Last Modified: 4/2/15 3:44:57 PM Permanent number: 12499 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQV3_PD S_Pediatric Demographi cs | PDQV3/PDS Pediatric Demographics option | This test checks the ability of your system to support the pediatric demographics option | Version: CATS2015 Last Modified: 4/2/15 3:45:10 PM Permanent number: 12500 | Gazelle Patient Manager GazelleHL7Vali dator |
| PDQV3_PD S_Prerequis ite | PDQV3/PDS Pre-Requisite | This test explains how to configure both your System and the tooling to perform the following test cases in the best conditions | Version: CATS2015 Last Modified: 4/2/15 11:34:19 AM Permanent number: 12560 | Gazelle Patient Manager GazelleHL7Vali dator |

3.5.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---------------------------|---|-------------------------|-----------------|-------------------------|------------------|
| PatientManager | Patient Manager | 9.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Vali dator | HL7 V2 and V3 Message Validator | 3.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |



3.6 Profile PIXv3

The Patient Identifier Cross-Referencing-V3 Profile enables the cross-referencing of patient identifiers from multiple Patient Identifier Domains.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:23, section from version 11.0 of this Technical Framework, issued September 29th 2014, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2014 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.6.1 Patient Id Cross-reference Consumer Actor

3.6.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|--|---|---|---|
| PIXV3_Qu ery | PIXV3: Patient Identifier Cross- Reference Consumer queries PIXV3 manager | This test checks that your SUT is able to query a PIXV3 manager | Version: CATS2015 Last Modified: 3/23/15 8:43:00 PM Permanent number: 12515 | Gazelle Patient Manager GazelleHL7Vali dator |

3.6.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---------------------------|--|-------------------------|-----------------|-------------------------|------------------|
| Gazelle PatientManager | Patient Manager | 9.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Validator | HL7 V2 and V3 Message Validator | 3.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.6.2 Patient Identity Cross Reference Manager Actor

One option may be selected by the SUT:

- Pediatric Demographics



3.6.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|--|--|---|
| PIXV3_Ma nager_Feed _Merge | PIXV3: Patient Identity Feed HL7V3 - Merge | This test checks that your SUT correctly integrates the Merge message received from a PIX Source | Version: CATS2015 Last Modified: 3/23/15 10:19:52 PM Permanent number: 12501 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Feed _W_known _dom | PIXV3: Feed Patient Identifier Cross- Reference Manager with a valid domain | This test checks that your SUT accept feeds for a patient with identifiers from a valid and known domain | Version: CATS2015 Last Modified: 3/23/15 10:02:50 PM Permanent number: 12502 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Feed _W_Unkno wn_dom | PIXV3: Feed Patient Identifier Cross- Reference Manager with an unknown domain | This test checks that your SUT does not accept feeds for a patient with identifiers from an unknown domain | Version: CATS2015 Last Modified: 3/23/15 10:04:20 PM Permanent number: 12503 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case1 | PIXV3: Query PIXV3 Manager (Case 1) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/25/15 11:19:07 AM Permanent number: 12505 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case2 | PIXV3: Query PIXV3 Manager (Case 2) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/23/15 9:11:56 PM Permanent number: 12504 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case3 | PIXV3: Query PIXV3 Manager (Case 3) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/23/15 9:13:47 PM Permanent number: 12506 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case4 | PIXV3: Query PIXV3 Manager (Case 4) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/23/15 9:18:43 PM Permanent number: 12507 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case5 | PIXV3: Query PIXV3 Manager (Case 5) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/23/15 10:13:15 PM Permanent number: 12508 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Quer y_Case6 | PIXV3: Query PIXV3 Manager (Case 6) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2015 Last Modified: 3/23/15 9:27:24 PM Permanent number: 12509 | Gazelle Patient Manager GazelleHL7Val idator |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|---|---|---|---|
| PIXV3_Ma nager_Upda te | PIXV3: Update Patient Identifier Cross-Reference Manager | This test checks that your SUT accept feeds and is able to update patients | Version: CATS2015 Last Modified: 3/23/15 9:38:49 PM Permanent number: 12510 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Upda te_Notificati o | PIXV3 Manager sends update notifications | We are testing the ability of your system to issue PIXV3 Update notification messages to a consumer which registered for such feeds | Version: CATS2015 Last Modified: 3/23/15 9:47:43 PM Permanent number: 12561 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_Ma nager_Upda te_unknown _dom | PIXV3: Update Patient Identifier Cross-Reference Manager with an unknown domain | This test checks that your SUT does not accept to update patient demographics when coming from an unknown domain | Version: CATS2015 Last Modified: 3/23/15 9:51:01 PM Permanent number: 12511 | Gazelle Patient Manager GazelleHL7Val idator |
| PIXV3_PD O_BirthInfo rmation | PIXV3: Query PIXV3 Manager PDO (Multiple Birth indicator and birth order) | This test checks that your SUT correctly supports the Pediatric Demographics Option | Version: CATS2015 Last Modified: 4/2/15 3:45:22 PM Permanent number: 12512 | Gazelle Patient Manager GazelleHL7Val idator |

3.6.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|---------------------------|--|-------------------------|-----------------|-------------------------|------------------|
| Gazelle PatientManager | Patient Manager | 9.2.2 | IHE-Europe | http://gazelle.ihe.net/ | Simulator |
| GazelleHL7Validator | HL7 V2 and V3 Message Validator | 3.2.1 | IHE-Europe | http://gazelle.ihe.net/ | Validator |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionnaire | 5.2.0 | IHE Europe | http://gazelle.ihe.net/ | Simulator |

3.7 Profile PIX

The Patient Identifier Cross-Referencing Profile enables the cross-referencing of patient identifiers from multiple Patient Identifier Domains.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:5, section from Rev. 12.1 Final Text of this Technical Framework, issued April 22th 2016, without any additional Final Text Change Proposals.



Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.7.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|---|--|----------------------------|
| PIX_Manag er_Feed_Me rge | PIX: Patient Identity Feed HL7 - Merge | This test checks that your SUT correctly integrates the Merge message received from a PIX Source | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12568 | Patient Manager |
| PIX_Manag er_Feed_W _known_do m | PIX: Feed Patient Identifier Cross- Reference Manager with a valid domain | This test checks that your SUT accept feeds for a patient with identifiers from a valid and known domain | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12578 | Patient Manager |
| PIX_Manag er_Feed_W _Unknown_ dom | PIX: Feed Patient Identifier Cross- Reference Manager with an unknown domain | This test checks that your SUT does not accept feeds for a patient with identifiers from an unknown domain | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12579 | Patient Manager |
| PIX_Manag er_Query_C ase1 | PIX: Query PIX Manager (Case 1) | This test checks that your SUT correctly answers to PIX queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12570 | Patient Manager |
| PIX_Manag er_Query_C ase2 | PIX: Query PIX Manager (Case 2) | This test checks that your SUT correctly answers to PIX queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12572 | Patient Manager |
| PIX_Manag er_Query_C ase3 | PIX: Query PIX Manager (Case 3) | This test checks that your SUT correctly answers to PIX queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12573 | Patient Manager |
| PIX_Manag er_Query_C ase4 | PIX: Query PIX Manager (Case 4) | This test checks that your SUT correctly answers to PIX queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12610 | Patient Manager |
| PIX_Manag er_Query_C ase5 | PIX: Query PIX Manager (Case 5) | This test checks that your SUT correctly answers to PIXV3 queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12574 | Patient Manager |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|--|--|----------------------------|
| PIX_Manag er_Query_C ase6 | PIX: Query PIX Manager (Case 6) | This test checks that your SUT correctly answers to PIX queries | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12575 | Patient Manager |
| PIX_Manag er_Update | PIX: Update Patient Identifier Cross- Reference Manager | This test checks that your SUT accept feeds and is able to update patients | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12567 | Patient Manager |
| PIX_Manag er_Update_ Notification | PIX Manager sends update notifications | We are testing the ability of your system to issue PIXV3 Update notification messages to a consumer which registered for such feeds | Version: CATS2016 Last modified: 2016-01- 21 Permanent number: 12569 | Patient Manager |
| PIX_Manag er_Update_ unknown_d om | PIX: Update Patient Identifier Cross- Reference Manager with an unknown domain | This test checks that your SUT does not accept to update patient demographics when coming from an unknown domain | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12576 | Patient Manager |
| PIX_PDO_ BirthInform ation | PIX: Query PIX Manager PDO (Multiple Birth indicator and birth order) | This test checks that your SUT correctly supports the Pediatric Demographics Option | Version: CATS2016 Last modified: 2016-04- 06 Permanent number: 12577 | Patient Manager |

3.7.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.7.2 Patient Identity Cross Reference Manager Actor

3.7.2.1 List of test cases

| Test Test case Test case description case ID name | Test Case and Supporting Test Data with test tool ID | • |
|---|---|---|
|---|---|---|



| | | | Version and Reference | |
|---------------|---|---|--|-----------------|
| PIX_Quer y | PIX: Patient Identifier Cross- Reference Consumer queries PIX manager | This test checks that your SUT is able to query a PIX manager | Version: CATS2016 Last modified: 2016-02- 10 Permanent number: 12566 | Patient Manager |

3.7.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.8 Profile PAM

The Patient Administration Management Profile enables the message exchanges to support patient identity and encounter information, as well as movements within an acute care encounter.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:14, section from Rev. 12.1 Final Text of this Technical Framework, issued April 22th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.8.1 Patient Demographic Consumer Actor

Two options may be selected by the SUT:

- Merge
- Link/Unlink



3.8.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------|---|---|--|----------------------------|
| PAM_PDC_Li nk | PAM: Identification Management (Link) for Patient Demographic Consumer | PAM Patient Identification Management, ITI-30 with the LINK/UNLINK option | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12636 | Patient Manager |
| PAM_PDC_M erge | PAM: Identification Management (Merge) for Patient Demographic Consumer | PAM Patient Identification Management, ITI-30 with the MERGE option | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12637 | Patient Manager |

3.8.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.8.2 Patient Demographic Supplier Actor

Two options may be selected by the SUT:

- Merge
- Link/Unlink

3.8.2.1 List of test cases for Link-Unlink Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|--|---|---|----------------------------|
| PAM_PDS_Lin k | PAM: Identification Management (Link) for Patient Demographic Supplier | PAM Patient Identification Management, ITI-30 with the LINK/UNLINK option | Version : CATS2016 Last modified : 2016-04- 04 Permanent number : 12643 | Patient Manager |



3.8.2.2 List of test cases for Merge Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|---|---|--|----------------------------|
| PAM_PDS_Me rge | PAM: Identification Management (Merge) for Patient Demographic Supplier | PAM Patient Identification Management, ITI-30 with the MERGE option | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12646 | Patient Manager |

3.8.2.3 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.8.3 Patient Encounter Consumer Actor

Four options may be selected by the SUT:

- Inpatient/Outpatient
- Maintain demographics
- Advanced encounter management
- Historic movement

3.8.3.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------|---|--|--|----------------------------|
| PAM_PEC_BA SIC | PAM: Encounter Management (Basic subset for Patient Encounter Consumer) | Patient Encounter Management, this test uses the trigger events required for all systems implementing ITI-31 | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12642 | Patient Manager |



3.8.3.2 List of test cases with Advanced Encounter Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------|--|--|--|----------------------------|
| PAM_PEC_A DVANCE | PAM: Encounter Management (Advanced Encounter Management) for Patient Encounter Consumer | This test is dedicated to the Advanced Encounter Management option defined for the ITI-31 transaction from the PAM profile | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12627 | Patient Manager |

3.8.3.3 List of test cases with Historic Movement Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------------|---|---|--|----------------------------|
| PAM_PEC_HI ST | PAM: Encounter Management (Historic Movement Management) for Patient Encounter Consumer | This test is dedicated to the Historic Movement Management option defined for the ITI-31 transaction from the PAM profile | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12629 | Patient Manager |
| PAM_PEC_HI ST_Scutiny | PAM: Encounter Management (Historic Movement) for PEC | This test is used to gather the URL of test instances in which you have been sent the ZBE segment | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12633 | Gazelle HL7 Validator |

3.8.3.4 List of test cases with Inpatient Outpatient Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------|--|--|---|----------------------------|
| PAM_PEC_IN _OUT | PAM: Encounter Management (Inpatient/Outpatient management) for Patient Encounter Consumer actor | This test is dedicated of the Inpatient:Outpatient management option of the PAM profile. | Version : CATS2016 Last modified : 2016-04- 04 Permanent number : 12630 | Patient Manager |



3.8.3.5 List of test cases with Maintain Demographics Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------------------|--|---|--|----------------------------|
| PAM_PEC_M AINTAIN_DE MOG | PAM Encounter - Maintain demographic option for Patient Encounter Consumer | Maintain Demographics option for the PEC actor | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12635 | Patient Manager |

3.8.3.6 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.8.4 Patient Encounter Supplier Actor

Four options may be selected by the SUT:

- Inpatient/ Outpatient
- Maintain demographics
- Advanced encounter management
- Historic movement

3.8.4.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------|---|--|--|----------------------------|
| PAM_PES_BA SIC | PAM: Encounter Management (Basic subset for Patient Encounter Supplier) | Patient Encounter Management, this test uses the trigger events required for all systems implementing ITI-31 | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12628 | Patient Manager |



3.8.4.2 List of test cases with Advanced Encounter Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------|---|--|--|----------------------------|
| PAM_PES_BA SIC | PAM: Encounter Management (Basic subset for Patient Encounter Supplier) | Patient Encounter Management, this test uses the trigger events required for all systems implementing ITI-31 | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12628 | Patient Manager |

3.8.4.3 List of test cases with historic movement option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------------|---|---|--|----------------------------|
| PAM_PES_HI ST | PAM: Encounter Management (Historic Movement Management) for Patient Encounter Supplier | This test is dedicated to the Historic Movement Management option defined for the ITI-31 transaction from the PAM profile | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12649 | Patient Manager |
| PAM_PES_HI ST_Scrutiny | PAM: Encounter Management (Historic Movement) for PES | This test is used to gather the URL of test instances in which you have sent the ZBE segment | Version: CATS2016 Last modified: 2016-04-04 Permanent number: 12634 | Gazelle HL7 Validator |

3.8.4.4 List of test cases with Inpatient Outpatient Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------|--|--|--|----------------------------|
| PAM_PES_IN _OUT | PAM: Encounter Management (Inpatient/Outpatient management) for Patient Encounter Supplier | This test is dedicated of the Inpatient:Outpatient management option of the PAM profile. | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12650 | Patient Manager |



3.8.4.5 List of test cases with maintain demographics option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------------------|--|--|--|----------------------------|
| PAM_PES_M AINTAIN_DE MOG | PAM Encounter - Maintain Demographic option for Patient Encounter Supplier | Maintain Demographics option for the PES | Version: CATS2016 Last modified: 2016-04- 04 Permanent number: 12651 | Patient Manager |

3.8.4.6 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-------------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |

3.9 Profile XCA

The Cross Community Access Profile Supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/ enterprises that have agreed to work together.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:18, section from Rev. 12.1 Final Text of this Technical Framework, issued April 22th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.



3.9.1 Initiating Gateway Actor

3.9.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|---|--|--|----------------------------|
| XC_Read_This _First | XC_Read_This_ First | Preparation for XCA, XCPD and/or XCA-I tests | Version: CATS2016 Last modified: 2016-04-08 Permanent number: 12654 | None |
| XCA_INIT_Fi ndDocuments_ LeafClass | XCA - Initiating Gateway - XGQ FindDocuments for LeafClass | XGQ FindDocuments for LeafClass [12300] | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12587 | XDS Toolkit |
| XCA_INIT_Fi ndDocuments_ ObjectRef | XCA - Initiating Gateway - XGQ FindDocuments for ObjectRef | XGQ FindDocuments for ObjectRef [12306] | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12586 | XDS Toolkit |
| XCA_INIT_Ge tDocuments | XCA - Initiating Gateway - XGQ GetDocuments | XGQ GetDocuments [12307] | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12588 | XDS Toolkit |
| XCA_INIT_Re trieve_multi_D oc | XCA - Initiating Gateway - Cross Gateway Retrieve of multiple documents | Cross Gateway Retrieve of a multiple documents [12308] | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12590 | XDS Toolkit |
| XCA_INIT_Re trieve_Single_ Doc | XCA - Initiating Gateway - Cross Gateway Retrieve of a single document | Cross Gateway Retrieve of a single document [12301] | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12589 | XDS Toolkit |
| XCA_INIT_X DS_Aff_Negati ve_tests | XCA - Initiating Gateway - XDS Affinity Domain Option - negative tests | Testing the IG with the option XDS Affinity Domain - Initiating Gateway negative tests [15814] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12668 | XDS Toolkit |
| XCA_INIT_X DS_Aff_Query _Single_RG | XCA - Initiating Gateway - XDS Affinity Domain Option - Query Single RG | Testing the IG with the option XDS Affinity Domain - Query Single Responding Gateway test [15808] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12665 | XDS Toolkit |
| XCA_INIT_X DS_Aff_Ret_Si ngle_RG | XCA - Initiating Gateway - XDS Affinity Domain Option - Retrieve Single RG | Testing the IG with the option XDS Affinity Domain - Retrieve Single Responding Gateway test [15809] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12666 | XDS Toolkit |
| XCA_INIT_X DS_Aff_SQ_R et_Two_RG | XCA - Initiating Gateway - XDS Affinity Domain Option - Query | Testing the IG with the option XDS Affinity Domain - Two Responding Gateway Response test [15810] | Version : CATS2016 Last modified : 2016-04- 07 Permanent number : | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | and Retrieve | | 12667 | |
| | Multiple RG | | | |

3.9.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------------------|---|-------------------------|-----------------|--|------------------------------|
| XDS Toolkit | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulato r & Validator |
| Syslog collector | Simulator for collecting syslog messages | 2.1 | MIR | http://ihewiki.wustl.edu/wiki/index.php/Syslo g_Message_Browser | Simulato r |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionn aire | 5.2.0 | IHE-Europe | http://gazelle.ihe.net/ | Simulato r & Validator |

3.9.2 Responding Gateway Actor

3.9.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|--|--|----------------------------|
| XC_Read_This _First | XC_Read_This_ First | Preparation for XCA, XCPD and/or XCA-I tests | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12654 | None |
| XCA_RESP_fi ndDoc_XDS | XCA - Responding Gateway - FindDocuments for LeafClass RG | FindDocuments for LeafClass RG test [15811] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12669 | XDS Toolkit |
| XCA_RESP_Fi ndDocuments_ LeafClass | XCA - Responding Gateway - XCQ FindDocuments for LeafClass | XCQ FindDocuments for ObjectRef [12310] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12582 | XDS Toolkit |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|---|--|--|----------------------------|
| XCA_RESP_Fi ndDocuments_ ObjectRef | XCA - Responding Gateway - XCQ FindDocuments for ObjectRef | XCQ FindDocuments for ObjectRef [12309] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12581 | XDS Toolkit |
| XCA_RESP_G etDocuments | XCA - Responding Gateway - XCQ GetDocuments Cross Community Query | XCQ GetDocuments [12311] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12583 | XDS Toolkit |
| XCA_RESP_In itialization | XCA - Responding Gateway - Test initialization | Establish test data in systems behind Responding Gateway. | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12580 | XDS Toolkit |
| XCA_RESP_N egative_Tests | XCA - Responding Gateway - Responding Gateway negative tests | Responding Gateway negative tests[15815] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12671 | XDS Toolkit |
| XCA_RESP_R etrieve_Multi_ Doc | XCA - Responding Gateway - XCR Retrieve multiple documents | XCR Retrieve Multiple Documents [12313] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12585 | XDS Toolkit |
| XCA_RESP_R etrieve_Single_ Doc | XCA - Responding Gateway - XCR Retrieve single document | XCR Retrieve Single Document [12312] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12584 | XDS Toolkit |
| XCA_RESP_R etrieve_XDS | XCA - Responding Gateway - Responding Gateway Retrieve | Responding Gateway Retrieve test [15813] | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12670 | XDS Toolkit |

3.9.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------|----------------------|-------------------------|-----------------|--|------------------------------|
| XDS Toolkit | XDS Tools 2 | 2.202.4 | NIST | http://ihexds.nist.gov/ | Simulato r & Validator |
| Syslog collector | Simulator for | 2.1 | MIR | http://ihewiki.wustl.edu/wiki/index.php/Syslo g_Message_Browser | Simulato r |



| | collecting syslog messages | | | | |
|------------------------------|---|-------|------------|-------------------------|------------------------------|
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionn aire | 5.2.0 | IHE-Europe | http://gazelle.ihe.net/ | Simulato r & Validator |

3.10 Profile XCPD

The Cross Community Patient Discovery Profile enables the message exchanges to support patient identity and encounter information, as well as movements within an acute care encounter.

The test methods specified in this section are based on the IHE Profile as specified in IHE ITI TF-1:27, section from Rev. 12.1 Final Text of this Technical Framework, issued April 22th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.10.1 Initiating Gateway Actor

One option may be selected by the SUT:

- Deferred Response

3.10.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|------------------------|------------------------|--|--|----------------------------|
| XC_Read_This _First | XC_Read_This_ First | Preparation for XCA, XCPD and/or XCA-I tests | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12654 | None |
| XCPD_IG_Que ry | XCPD/IG Query | This test evaluates the capability of the IG SUT to send a valid query to the PatientManager tool acting as a XCPD Responding Gateway | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12653 | Patient Manager |



3.10.1.2 List of test cases with Deferred Response Option

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------------------|---|---|--|----------------------------|
| XCPD_IG_Def erred_Response | XCPD/IG Deferred Response Option | Test the ability of XCPD IG with Deferred Response Option to send valid request | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12655 | Patient Manager |

3.10.1.3 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------------------|---|-------------------------|-----------------|--|------------------------------|
| Syslog collector | Simulator for collecting syslog messages | 2.1 | MIR | http://ihewiki.wustl.edu/wiki/index.php/Syslo g_Message_Browser | Simulato r |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionn aire | 5.2.0 | IHE-Europe | http://gazelle.ihe.net/ | Simulato r & Validator |
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |

3.10.2 Responding Gateway Actor

3.10.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------------------------|---|--|--|----------------------------|
| XC_Read_This _First | XC_Read_This_ First | Preparation for XCA, XCPD and/or XCA-I tests | Version: CATS2016 Last modified: 2016-04- 08 Permanent number: 12654 | None |
| XCPD_RG_De ferred_Respons e | XCPD/RG Deferred Response Option | Test the ability of XCPD RG with Deferred Response Option to receive valid request | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12656 | Patient Manager |
| XCPD_RG_ITI 55 | XCPD/RG ITI- 55 requests | Test the ability of the RG to respond to ITI-55 requests | Version : CATS2016 Last modified : 2016-04- | Patient Manager |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|--|---|--|----------------------------|
| | | | 07 Permanent number : 12645 | |
| XCPD_RG_ITI 55_responsePri ority | XCPD/RG responsePriority Code processing | The RG SHALL be able to process the responsePriorityCode | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12652 | Patient Manager |
| XCPD_RG_Pre requisite | XCPD/RG Prerequisite | This test explains how to configure both your System and the tooling to perform the following test cases in the best conditions | Version: CATS2016 Last modified: 2016-04- 07 Permanent number: 12644 | Patient Manager |

3.10.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------------------|---|-------------------------|-----------------|--|------------------------------|
| Syslog collector | Simulator for collecting syslog messages | 2.1 | MIR | http://ihewiki.wustl.edu/wiki/index.php/Syslo g_Message_Browser | Simulato r |
| Gazelle Security Suite | PKI, TLS Simulator and ATNA Questionn aire | 5.2.0 | IHE-Europe | http://gazelle.ihe.net/ | Simulato r & Validator |
| Patient Manager | Gazelle Patient Manager | 9.2.2 | IHE-Europe | https://gazelle.ihe.net | Simulato r |

3.11 Profile LAW

The Laboratory Analytical WorkflowProfile supports the analytical workflow between analyzers (an IVD device) of the clinical laboratory and the systems managing their work such as a LAS or a LIS. Both patient and quality control (QC) specimens are in scope.

The test methods specified in this section are based on the IHE Profile as specified in the final text IHE PaLM Supplement Final Text of this Technical Framework, issued February 24th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after January 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:



- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.11.1 Analyzer Actor

3.11.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---------------------------------------|--|---|--|----------------------------|
| LAW_AN_AW OS_Manual | LAW Normal Process With AWOS Manual Entry (for Analyzer) | In this test, the Analyzer participant will enter the AWOS manually, no previous AWOS broadcast is received. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12614 | Order Manager |
| LAW_AN_AW OS_Update | LAW AWOS Update Prior To Specimen Arrival (for Analyzer) | This test concerns the update of an Analytical Work Order triggering the update of its AWOS. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12612 | Order Manager |
| LAW_AN_Ma nual_Urgent_A WOS | LAW Manual Urgent AWOS (for Analyzer) | In this test, the Analyzer Manager receives the Work Order after that the Analyzer has performed the test. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12613 | Order Manager |
| LAW_AN_Nor mal_Process _W_Query | LAW Normal Process When Analyzers Query | In this use case, the Analyzer queries the Analyzer Manager for WOS related to the specimen. The Analyzer Manager sends the scheduled list of AWOS. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12615 | Order Manager |
| LAW_AN_Ref lex_By_Analyz er | LAW Reflex Decided On The Analyzer Immediately After First Run (for Analyzer) | In this test, the Analyzer needs to performs a new test after the first test. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12617 | Order Manager |
| LAW_AN_Rer un_By_Analyz | LAW Rerun Decided On The Analyzer | In this test, the Analyzer performs a second run immediately after the | Version : CATS2016 Last modified : 2016-03- 17 | Order Manager |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---|--|---|--|----------------------------|
| er | Immediately After first Run (for Analyzer) | first run. | Permanent number: 12618 | |
| LAW_AWOS_ PRIORITY_C ONFORMANC E | Scrutiny of messages for LAW_AWOS_P RIORITY option | Analyzers implementing the LAW_AWOS_PRIORITY options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12598 | Gazelle HL7 Validator |
| LAW_AWOS_ Received_Prior _To_Speci | LAW AWOS Received Prior To Specimen Arrival | In this test, the Analyzer receives the AWOS from the analyzer Manager, performs the test and notifies the Analyzer Manager of the completion of the AWOS. | Version: CATS2016 Last modified: 2016-03- 17 Permanent number: 12611 | Gazelle HL7 Validator |
| LAW_CONTR IB_SUB_CON FORMANCE | Scrutiny of messages for LAW_CONTRI B_SUB option | Analyzers implementing the LAW_CONTRIB_SUB options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12591 | Gazelle HL7 Validator |
| LAW_DILUTI ONS_CONFO RMANCE | Scrutiny of messages for LAW_DILUTI ONS option | Analyzers implementing the LAW_DILUTIONS options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12592 | Gazelle HL7 Validator |
| LAW_MASS_ SPEC_CONFO RMANCE | Scrutiny of messages for LAW_MASS_S PEC option | Analyzers implementing the LAW_MASS_SPEC option are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12603 | Gazelle HL7 Validator |
| LAW_PAT_D EM_CONFOR MANCE | Scrutiny of messages for LAW_PAT_DE M option | Analyzers implementing the LAW_PAT_DEM options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12593 | Gazelle HL7 Validator |
| LAW_POOL_ | Scrutiny of | Analyzers implementing the | Version : CATS2016 | Gazelle HL7 |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|------------------------------------|--|---|--|----------------------------|
| AN_CONFOR MANCE | messages for LAW_POOL_A N option | LAW_POOL_AN option are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Last modified: 2016-03- 07 Permanent number: 12606 | Validator |
| LAW_POOL_ NOAN_CONF ORMANCE | Scrutiny of messages for LAW_POOL_N OAN option | Analyzers implementing the LAW_POOL_NOAN option are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12609 | Gazelle HL7 Validator |
| LAW_RESUL T_EXT_CONF ORMANCE | Scrutiny of messages for LAW_RESULT _EXT option | Analyzers implementing the LAW_RESULT_EXT option are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12605 | Gazelle HL7 Validator |
| LAW_SPECIM EN_CONFOR MANCE | Scrutiny of messages for LAW_SPECIM EN option | Analyzers implementing the LAW_SPECIMEN options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12600 | Gazelle HL7 Validator |

3.11.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-----------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |
| Order Manager | Gazelle Order Manager | 4.2.3 | IHE-Europe | https://gazelle.ihe.net | Simulato r |

3.11.2 Analzer Manager



3.11.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--|---|--|--|----------------------------|
| LAW_AM_A WOS_Manual | LAW Normal Process With AWOS Manual Entry (for Analyzer Manager) | In this test, the Analyzer participant will enter the AWOS manually, no previous AWOS broadcast is received. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12621 | Order Manager |
| LAW_AM_A WOS_PRIORI TY_CONFOR MANCE | Conformance testing of messages for Analyzer Manager interacting with Analyzer supporting LAW_AWOS_P RIORITY option | Analyzer Managers which communicate with an Analyzer implementing the LAW_AWOS_PRIORITY options are expected to transmit some extra data. This test is expected to make sure the produced messages are conformant to the profile. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12599 | Gazelle HL7 Validator |
| LAW_AM_A WOS_Update | LAW AWOS Update Prior To Specimen Arrival (For Analyzer Manager) | This test concerns the update of an Analytical Work Order triggering the update of its AWOS. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12624 | Order Manager |
| LAW_AM_CO NTAINER_CO NFORMANCE | Conformance review of messages for Analyzer Manager interacting with Analyzer supporting LAW_CONTAI NER option | Analyzer Managers which communicate with an Analyzer implementing the LAW_CONTAINER options are expected to transmit some extra data. This test is expected to ensure conformance testing for elements described by this option in the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12602 | Gazelle HL7 Validator |
| LAW_AM_Ma nual_Urgent_A WOS | LAW Manual Urgent AWOS (For Analyzer Manager) | In this test, the Analyzer Manager receives the Work Order after that the Analyzer has performed the test. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12623 | Order Manager |
| LAW_AM_No rmal_Process | LAW Normal Process When | In this use case, the Analyzer queries the Analyzer Manager for | Version : CATS2016 Last modified : 2016-03- | Order Manager |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-------------------------------------|--|--|---|----------------------------|
| _W_Query | Analyzers Query (for Analyzer Manager) | WOS related to the specimen. The Analyzer Manager sends the scheduled list of AWOS. | 07 Permanent number : 12620 | |
| LAW_AM_PO OL_AN_CON FORMANCE | Scrutiny of messages for Analyzer Manager interacting with Analyzer supporting LAW_POOL_A N option | Analyzer Managers which communicate with an Analyzer implementing the LAW_POOL_AN option are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12607 | Gazelle HL7 Validator |
| LAW_AM_PO OL_NOAN_C ONFORMITY | Scrutiny of messages for Analyzer Manager interacting with Analyzer supporting LAW_POOL_N OAN option | Analyzer Managers which communicate with an Analyzer implementing the LAW_POOL_NOAN options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12608 | Gazelle HL7 Validator |
| LAW_AM_Ref lex_By_Analyz er | LAW Reflex Decided On The Analyzer Immediately After First Run (for Analyzer Manager) | In this test, the Analyzer needs to performs a new test after the first test. | Version : CATS2016 Last modified : 2016-03- 07 Permanent number : 12625 | Order Manager |
| LAW_AM_RE L_OBS_CONF ORMANCE | Scrutiny of messages for Analyzer Manager interacting with Analyzer supporting LAW_REL_OB S option | Analyzer Managers which communicate with an Analyzer implementing the LAW_REL_OBS options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12604 | Gazelle HL7 Validator |
| LAW_AM_Rer un_By_Analyz er | LAW Rerun Decided On The Analyzer Immediately | In this test, the Analyzer performs a second run immediately after the first run. | Version : CATS2016 Last modified : 2016-03- 07 Permanent number : | Order Manager |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|---|---|---|--|----------------------------|
| | After first Run (for Analyzer Manager) | | 12626 | |
| LAW_AM_RR _CONFORMA NCE | Scrutiny of messages for LAW_RERUN_ REFLEX option | Analyzer Managers implementing the LAW_RERUN_REFLEX options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12596 | Gazelle HL7 Validator |
| LAW_AM_RR _CONTROL_C ONFORMANC E | Scrutiny of messages for LAW_AM_RR_ CONTROL option | Analyzer Managers implementing the LAW_AM_RR_CONTROL options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12597 | Gazelle HL7 Validator |
| LAW_AM_SP ECIMEN_CO NFORMANCE | Scrutiny of messages for Analyzer Manager interacting with Analyzer supporting LAW_SPECIM EN option | Analyzer Managers which communicate with an Analyzer implementing the LAW_SPECIMEN options are expected to transmit some extra data. This test is expected to make sure of the conformance of the messages. | Version: CATS2016 Last modified: 2016-03- 07 Permanent number: 12601 | Gazelle HL7 Validator |

3.11.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|-----------------------------|-----------------------------|-------------------------|-----------------|-------------------------|----------------------|
| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE-Europe | https://gazelle.ihe.net | Validator |
| Order Manager | Gazelle Order Manager | 4.2.3 | IHE-Europe | https://gazelle.ihe.net | Simulato r |



3.12 Profile XDS-I

The Cross-Enterprise Document Sharing for Imaging Profile Supports the sharing (publishing, finding and retrieving) documents across a group of affiliated enterprises. It extends and specializes the mechanisms defined by XDS.b to support imaging "documents".

The test methods specified in this section are based on the IHE Profile as specified in IHE RAD TF-1:18, section from Rev. 14.0 Final Text of this Technical Framework, issued July 24th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.12.1 Imaging Document Consumer Actor

The following list of test cases and list of related test tools are being developed and may be updated in a later version of the CAS-2.

3.12.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | | | | |

3.12.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|-----------------|----------------|-------------------------|-----------------|------------------------|------------------|
| | | | | | |

3.12.2 Imaging Document Sourcer Actor

Four options may be selected by the SUT and are not subject to Conformity Assessment:

- Set of DICOM Instances
- PDF Report
- CDA Wrapped Text Report
- CDA Imaging Report with Structured Headings



The following list of test cases and list of related test tools are being developed and may be updated in a later version of the CAS-2.

3.12.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | | | | |

3.12.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|-----------------|----------------|-------------------------|-----------------|------------------------|------------------|
| | | | | | |

3.13 Profile XCA-I

The Cross-Community Access for Imaging Profile supports query and retrieve patient-relevant medical imaging data being held by other communities It extends the IT Infrastructure XCA Profile by providing access to diagnostic reports, imaging Manifests and the imaging objects referenced in the Manifests.

The test methods specified in this section are based on the IHE Profile as specified in IHE RAD TF-1:29, section from Rev. 14.0 Final Text of this Technical Framework, issued July 24th 2016, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.13.1 Initiating Imaging Gateway

The following list of test cases and list of related test tools are being developed and may be updated in a later version of the CAS-2.

3.13.1.1 List of test cases



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | | | | |

3.13.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|-----------------|----------------|-------------------------|-----------------|------------------------|------------------|
| | | | | | |

3.13.2 Responding Imaging Gateway

The following list of test cases and list of related test tools are being developed and may be updated in a later version of the CAS-2.

3.13.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | | | | |

3.13.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|-----------------|----------------|-------------------------|-----------------|------------------------|------------------|
| | | | | | |

3.14 Profile DEC

The Device Enterprise Communication Profile Supports communication of vendor independent, multi-modality Patient Care Devices data to Enterprise Applications using consistent semantics.

The test methods specified in this section are based on the IHE Profile as specified in IHE PCD TF-1:3, section from Rev. 5.0 Final Text of this Technical Framework, issued October 14th 2015, without any additional Final Text Change Proposals.

Final Text CPs that were approved after September 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.



- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.14.1 Device Observation Consumer Actor

3.14.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------|-----------------------------------|--|--|----------------------------|
| DEC DOC POI SUT | DEC_DOR_D OC_POI_(DO C_SUT) | Evaluates the capability of a DEC DOC which supports POI to consume valid PCD-01 messages from a DOR and transmit the Accept ACKs. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12660 | NIST PCD Tool |
| DEC DOC SUT | DEC_DOR_D OC_(DOC_S UT) | Evaluates the capability of a DEC DOC to consume valid PCD-01 messages from a DOR and transmit the Accept ACKs. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12658 | NIST PCD Tool |

3.14.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------|----------------------|-------------------------|-----------------|--|------------------------------|
| NIST PCD Tool | NIST PCD Tool | 1.6 | NIST | http://ihe-pcd-precon.nist.gov/PCD- HL7WebPreCon/ | Simulato r & Validator |

3.14.2 Device Observation Reporter Actor

3.14.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|--------------------|-----------------------------------|--|--|----------------------------|
| DEC DOR POI SUT | DEC_DOR_D OC_POI_(DO R_SUT) | Evaluates the capability of a DEC DOR which supports POI to transmit valid PCD-01 messages to a DOC and consume the Accept ACKs. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12659 | NIST PCD Tool |
| DEC DOR SUT | DEC_DOR_D OC_(DOR_S UT) | Evaluates the capability of a DEC DOR to transmit valid PCD-01 messages to a DOC and consume the Accept ACKs. | Version : CATS2016 Last modified : 2016- 04-07 Permanent number : | NIST PCD Tool |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|-------------------|-----------------------|---|----------------------------|
| | | | 12657 | |

3.14.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------|----------------------|-------------------------|-----------------|--|------------------------------|
| NIST PCD Tool | NIST PCD Tool | 1.6 | NIST | http://ihe-pcd-precon.nist.gov/PCD-HL7WebPreCon/ | Simulato r & Validator |

3.15 Profile PIV

The Patient Administration Mana Point-of-care Infusion Verification Profile Supports the electronic transfer of infusion parameters from a Bedside Computer assisted Medication Administration (BCMA) system to a general-purpose infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking and increase caregiver productivity.

The test methods specified in this section are based on the IHE Profile as specified in IHE PCD TF-1:4, section from Rev. 5.0 Final Text of this Technical Framework, issued October 14th 2015, without any additional Final Text Change Proposals.

Final Text CPs that were approved after March 1st, 2016 are not in scope of this profile Conformity Assessment. This implies that:

- Systems Under Test may implement such additional Final Test CPs.
- In case, a SUT does not pass a test case due to the implementation of such an additional CP, the Authorized Test Laboratory shall consider the test case passed with a comment.

3.15.1 Infusion Order Programmer Actor

3.15.1.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------------------|---|---|--|----------------------------|
| PIV IOP Piggyback SUT | PIV_IOP_IOC _Piggyback_(I OP_SUT) | Evaluates the capability of a PIV IOP to transmit valid PCD-03 messages indicating piggyback to a IOC and consume the Accept Acknowledgement and Application Acknowledgement messages. This test requires one | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12663 | NIST PCD Tool |



| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------|---------------------------|---|--|----------------------------|
| | | pump. | | |
| PIV IOP SUT | PIV_IOP_IOC _(IOP_SUT) | Evaluates the capability of a PIV IOP to transmit valid PCD-03 messages to a IOC and consume the Accept Acknowledgement and Application Acknowledgement messages. This test requires two pumps. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12661 | NIST PCD Tool |

3.15.1.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Catego ry |
|------------------|----------------------|-------------------------|-----------------|--|------------------------------|
| NIST PCD Tool | NIST PCD Tool | 1.6 | NIST | http://ihe-pcd-precon.nist.gov/PCD- HL7WebPreCon/ | Simulato r & Validator |

3.15.2 Infusion Order Consumer Actor

3.15.2.1 List of test cases

| Test Case ID | Test Case Name | Test Case Description | Test Case and Test Data with Version and Reference | Supporting Test Tool ID |
|-----------------------------|---|--|--|----------------------------|
| PIV IOC Piggyback SUT | PIV_IOP_IOC _Piggyback_(I OC_SUT) | Evaluates the capability of a PIV IOC to receive valid PCD-03 messages indicating piggyback from an IOP and transmit the Accept Acknowledgement and Application Acknowledgement messages. This test requires one pump. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12664 | NIST PCD Tool |
| PIV IOC SUT | PIV_IOP_IOC _(IOC_SUT) | Evaluates the capability of a PIV IOC to receive valid PCD-03 messages from an IOP and transmit the Accept Acknowledgement and Application Acknowledgement messages. This test requires two pumps. | Version: CATS2016 Last modified: 2016- 04-07 Permanent number: 12662 | NIST PCD Tool |

3.15.2.2 List of related test tools

| Test Tool ID | Test Tool Name | Test Tool Version | Deve lope d by | Test Tool Info Page | Tool Category |
|-----------------|-------------------|-------------------------|----------------------|---------------------|------------------|
|-----------------|-------------------|-------------------------|----------------------|---------------------|------------------|



| Gazelle HL7 Validator | Gazelle HL7 Validator | 3.2.1 | IHE- Europ e | https://gazelle.ihe.net | Validator |
|-----------------------------|--------------------------|-------|--------------------|--|--------------------------|
| NIST PCD Tool | NIST PCD Tool | 1.6 | NIST | http://ihe-pcd-precon.nist.gov/PCD- HL7WebPreCon/ | Simulator & Validator |



4 Support tools

| Test Tool ID | Test Tool Name | Test Tool Version | Developed by | Test Tool Info Page | Tool Category |
|----------------------------|---|-------------------------|-----------------|-------------------------|-----------------|
| Gazelle Test Management | The Gazelle Test Management Test Bed | 5.2.0 | IHE Europe | http://gazelle.ihe.net/ | Test Management |
| Demographic Data Server | Generate fake demographics for testing purposes | 3.0.0 | IHE Europe | http://gazelle.ihe.net | Data generation |
| SVS Simulator | Value Set repository | 2.0.3 | IHE Europe | http://gazelle.ihe.net | Date generation |



Appendix A – Templates

A.1 IHE-CAS-2 Template to Specify Test Cases

A Test Case is made of a series of test scripts (Gazelle calls it a test) to test a specific profile/actor.

A Test Case assembles all test scripts in which the SUT (System under Test) plays one of the ROLES for which the test script has been specified.

| Test Case Specification | | | |
|-----------------------------|--|------------------|-------------------------|
| Test case Identification | Test Case name | ID issued by IHE | Version assigned by IHE |
| Test Case Approved | Yes / No | Date | Who |
| Roles Tested | ROLE1, ROLE2, etc. (a ROLE is a list Actor/Profile/Option combination to which the case applies) (e.g. for XDS, 3 ROLEs: (1) XDS Doc Source,(2) XDS Doc Repository,(3) XDS Doc Registry) | | |

⁺⁺May be extended with other participants

A.2 IHE-CAS-2 Template to Report Test Case Execution

Template for reporting the execution of a test case. Note that the yellow elements are those coming from the test case specification template. The "brown" elements, cover the participants which number is specific to the test case.



| Test Case Execution | | | |
|--|--|------------------|-------------------------|
| Test case Identification | Test Case name | ID issued by IHE | Version assigned by IHE |
| Test Case Approved | Yes / No | Date | Who approves: |
| Roles Tested | ROLE1, ROLE2, etc. (a ROLE is a list Actor/Profile/Option combination to which the case applies) (e.g. for XDS, 3 ROLEs: (1) XDS Doc Source,(2) XDS Doc Repository,(3) XDS Doc Registry) | | |
| Test Execution | Start/StopTime Stamp | ID | Who executes: |
| Test Results Validation | Time Stamp | Pass/Fail | Who validates: |
| Overall Test Case Execution and Evaluation Notes | | | |
| Participant 1 | NAME of ROLE NAME tested | | |
| Product Id | Id used in the test result tracking by the Test Laboratory. | | |
| Customer Name | Organization submitting the product for testing | | |
| Product Name | Commercial Product Name | | |
| Version / Release | Commercial Product Version | | |
| Participant 2 (++) | NAME of ROLE NAME tested | | |
| Product Id | Id used in the test result tracking by the Test Laboratory. | | |
| Customer Name | Organization submitting the product for testing | | |
| Product Name | Commercial Product Name | | |
| Version / Release | Commercial Product Version | | |

A3 IHE-CAS-2 Template to Summarize Test Execution

This Summary Report template is used by an IHE International Authorized Testing Laboratory to summarize the execution of test cases by a System Under Test.





IHE International

Conformity Assessment - Summary Test Report

[Insert Test Laboratory Logo within this frame]

[Authorization #]

IHE International Conformity

Assessment Program

IHE-CAS-2: [date]

[Test Date]

[Insert System Under Test Corporate Logo within this frame]

Company Name Product Name Version Number The productand version documented in this report was tested by an IHE International-authorized testing laboratory in accordance with ISO/IEC 17025 requirements and the IHE Conformity Assessment Scheme (IHE-CAS) to demonstrate conformance with the IHE International profiles and actors identified in this report.

It provides a third-party conformity assessment of the product's adherence to one or more IHE Profiles. It demonstrates that the prouct is capable of assisting healthcare providers and hospitals in meeting requirements for clinical integration.

Testing was conducted as specified in the IHE-CAS-1 and IHE-CAS-2 documents. Testing consisted of observed demonstrations in a controlled location under normal operating conditions and using approved test tools. Test efforts also included review of test tool results, se fattestation materials and, where applicable, interoperability testing files and audit logs. Testing was constrained to the use of the IHE International technical frameworks specified in IHE-CAS-2 at the time of testing. Any exceptions to these requirements are noted within this test report, when applicable.

About [Test Lab] and [Regional/National Deployment Committee]

[Text Laboratory Name] is authorised by IHT International (Authorisation in [Text Lab Authorisation Internation Internation Internation International Internatio

Appendix 6 of this tot report will document any specific additional testing requirements per the regional or national IMS decloyment Committee.

For commonts or suggestions on this Conformity Assessment program, please confact [info @doployement the not]

IHS Test Laboratory Authoritation: [Testias Authorisation #] + Report IO: [Test Lab Report IO]

Page 1 of 6



IHE International Conformity Assessment Summary Test Report



Profiles/Actors Tested for Conformity Assessment

The IHE AuthorizedTesting Laboratory [Test Laboratory Name] determined that:

[Product Name] [Version] provided for conformity assessment by

[Company] located at [Address]

successfully demonstrated compliance to the selected profile/actor pairs for the IHE International Conformity Assessment Program per IHE-CAS-1 [date] and IHE-CAS-2 [date].

The System Under Test was made available for test on [date].

Tests were executed between [date] and [date] at location [Location City, Country].

| IHE Profile | Actor and Options | Test Result |
|---|-------------------|--------------------------|
| [IHE Domain | n Name] | 18 |
| Example: IHE-CT | Time Client: | \$1. |
| Consistent Time enables system clocks and time stamps of computers in a network to be synchronized (median error less than 1 second). | - No Option | Pass, Pass with Comments |
| [IHE Domain | Name] / | |
| IHE-Profile Tested | Actor 1 | Pass, Pass with Comments |
| | Actor 2 | Pass, Pass with Comment |
| IHE-Profile Tested | Actor 1 | Pass, Pass with Compats. |

(REText Laboratory Authorization: [Text Lab Authorization#] + Report (Cr.[Text Lab Report (C)]

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Additional Software Required for Testing

The following additional software/options were required by [Product/Version] from [Company] to assist in demonstrating compliance with the associated conformance requirements by providing the specified functionality:

| Software Product and Company | Associated Profiles/Actors | Functionality Provided |
|---------------------------------|-------------------------------|------------------------|
| None | | |

INSTED Laboratory Authoritation: [TestLab Authorisation#] + Report IO: [Test Lab Report IO]

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Report Summary

[Testing Laboratory], an IHE International Authorized Testing Laboratory attests that [Company/Product/Version] successfully passed the test cases identified in this report through attestation, observed demonstration, review of audit logs, and/or interoperability file validations. Testing was conducted using IHE-CAS-2; [date] testing processes based on ISO/IEC 17025. All test results documented in this report including the exceptions mentioned, are considered formal test results. This test results summary is issued by:

| Test Lab Authorized Representative Function/Title Signature and Date Please visit www.ihe.org/conformityassessment for the most current inform IHE Conformity Assessment program. Copyright [current year] [Test Lab]. All Rights Reserved. Test reports shall not be reproduil, without prior written approval of [Test Lab] or [IHE International] About [Test Laboratory] IHE International Authorization #: [Test Lab Authorizations, nother contact information.] | |
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| About [Test Laboratory] About [Test Laboratory] Insert text about Test Laboratory, including qualifications, other contact information. | |
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| | |
| [Insert Test Laboratory Address] [Insert Test Laboratory Contact Information] | |
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| (\$ Text Laboratory Author bable to [Text Lab Author bation #] + Report (0; [Text Lab Report (0)] | Sage 4 of |
| | |







Appendix A - Testing Comments

This Appendix documents or references any exceptions identified during testing.

| IHE Profile | Actor and Required Options | Test Cases Comments | Test Tools |
|-----------------------|--|--|---|
| | | [IHE Domain Name] / [Technical Frame | ework version] |
| Example: IHE- CT | Time Client: - No Option | Name and Version Name and Version Name and Version Name and Version Pass, Pass with Comments (#) | Name1 and Version Name2 and Version Name3 and Version |
| | | [IHE Domain Name] / [Technical Frame | ework version] |
| IHE-Profile Tested | Actor 1 | Name and Version Name and Version Name and Version Pass, Pass with Comments | Name1 and Version Name2 and Version |
| | Actor 2 | Name and Version Pass, Pass with Comments | Name3 and Version Name4 and Version |
| IHE-Profile Tested | Name and Version Pass, Pass with Competts. | | Name1 and Version Name2 and Version |

Additional Software Required for Testing with Exceptions:

| Software Product and Company | Associated Profiles/Actors | Exception identified during testing |
|---------------------------------|-------------------------------|-------------------------------------|
| None | None | None |

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IHE International Conformity Assessment Summary Test Report



Appendix B: (Optional) Regional/National Extensions Testing

Appendix B of this test report document or reference any specific additional regional or national IHE Deployment Committee testing requirements performed by this testing lab for the named product and version. If not such testing was performed, this Appendix shall be removed.

The test or certification report summaries in this Appendix B fall under the responsibility of [IHE National/Regional Deployment Committee].

Note: The testing of these extensions is related to one or more of the IHE Profiles/Actors object of this IHE International test Report. The testing/certification scheme and supporting test methods used to perform such testing has been specified by the IHE National/Regional Deployment Committee and is distinct from the IHE International scheme and specified test methods.

(NETest Laboratory Authorization: Test Lab Authorization#) + Report (C: Test Lab Report (C)

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