The “new” HL70078 table

Laurent Lardin, MSCS, BioMerieux
Riki Merrick, MPH, Contractor to APHL

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Background

- HL70078 table is used in OBX-8
  - Formally called Abnormal Flags
  - Now called Test Interpretation
- HL7 OO WG reviewed terms in both v2.x and compared to v3 ObservationInterpretation codes

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The results

9 categories of interpretations covered

- interpretations of numeric results in relation to reference ranges
- interpretations across numeric results over time
- interpretations across results over time assessment of including patient condition
- interpretations of results in relation to reference ranges, typically for non-numeric observations
- interpretations of results without indication to normal ranges
- interpretations of susceptibility testing
- information about why test result was not obtained
- interpretation of a genetic test result
- exclusion criteria for study participation

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Interpretations of susceptibility testing (1)

Code	Concept Name	Defintion
R	Resistant. Indicates for microbiology susceptibilities only.	Bacterial strain inhibited in vitro by a concentration of an antimicrobial agent that is associated with a high likelihood of therapeutic failure. [Note 1: Bacterial strains are categorized as resistant by applying the appropriate breakpoints in a defined phenotypic test system.] [Note 2: This breakpoint can be altered due to changes in circumstances (e.g., changes in commonly used drug dosages, emergence of new resistance mechanisms).]
I	Intermediate. Indicates for microbiology susceptibilities only.	Bacterial strain inhibited in vitro by a concentration of an antimicrobial agent that is associated with uncertain therapeutic effect. [Note 1: Bacterial strains are categorized as intermediate by applying the appropriate breakpoints in a defined phenotypic test system.] [Note 2: This class of susceptibility implies that an infection due to the isolate can be appropriately treated in body sites where the drugs are physiologically concentrated or when a high dosage of drug can be used.] [Note 3: This class also indicates a "buffer zone," to prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations.] [Note 4: These breakpoints can be altered due to changes in circumstances (e.g., changes in commonly used drug dosages, emergence of new resistance mechanisms).]
S	Susceptible. Indicates for microbiology susceptibilities only.	Bacterial strain inhibited by in vitro concentration of an antimicrobial agent that is associated with a high likelihood of therapeutic success Synonym (earlier term): Sensitive [Note 1: Bacterial strains are categorized as susceptible by applying the appropriate breakpoints in a defined phenotypic system.] [Note 2: This breakpoint can be altered due to changes in circumstances (e.g., changes in commonly used drug dosages, emergence of new resistance mechanisms).]

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Interpretations of susceptibility testing (2)

Code	Concept Name	Defintion
NS	Non susceptible	A category used for isolates for which only a susceptible interpretive criterion has been designated because of the absence or rare occurrence of resistant strains. Isolates that have MICs above or zone diameters below the value indicated for the susceptible breakpoint should be reported as nonsusceptible. Reference: AST reporting categoories -- Synonym: decreased susceptibility [Note 1: An isolate that is interpreted as nonsusceptible does not necessarily mean that the isolate has a resistance mechanism. It is possible that isolates with MICs above the susceptible breakpoint that lack resistance mechanisms may be encountered within the wild-type distribution subsequent to the time the susceptible-only breakpoint is set.] [Note 2: For strains yielding results in the “nonsusceptible” category, organism identification and antimicrobial susceptibility test results should be confirmed.]
SDD	Susceptible-dose dependent	A category that includes isolates with antimicrobial agent minimum inhibitory concentrations (MICs) that approach usually attainable blood and tissue levels and for which response rates may be lower than for susceptible isolates. Reference: CLSI document M44-A2 2009 “Method for antifungal disk diffusion susceptibility testing of yeasts; approved guideline – second edition” – page 2.
IE	EUCAST ‘Insufficient Evidence’	There is insufficient evidence that the species in question is a good target for therapy with the drug. A categorical interpretation is not possible. [Note: A MIC with "IE" and/or a comment may be reported (without an accompanying S, I or R-categorization).]

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Interpretations of numeric results in relation to reference ranges

Code	Concept Name	Definition
<	Below absolute low-off instrument scale	The result is below the minimum detection limit (the test procedure or equipment is the limiting factor). Synonyms: Below analytical limit, low off scale
>	Above absolute high-off instrument scale	The result is above the maximum quantifiable limit (the test procedure or equipment is the limiting factor). Synonyms: Above analytical limit, high off scale
LL	Below lower panic limits	The result for a quantitative observation is below a reference level at which immediate action should be considered for patient safety (as defined for the respective test procedure). Synonym: Below lower panic limits
L<	Between 'below low normal' and 'below critical limit'	The result for a quantitative observation is below a reference level at which action may be considered in the interest of the patient's health (as defined for the respective test procedure). [Note: This level is situated between 'L' and 'LL'.]
L	Below low normal	The result for a quantitative observation is below the lower limit of the reference range (as defined for the respective test procedure). Synonym: Below low normal
N	Normal (applies to non-numeric results)	The result or observation value is within the reference range or expected norm (as defined for the respective test procedure). [Note: Applies to numeric or non-numeric results.]
H	Above high normal	The result for a quantitative observation is above the upper limit of the reference range (as defined for the respective test procedure). Synonym: Above high normal
H>	Between 'above high normal' and 'above critical limits'	The result for a quantitative observation is above a reference level at which action may be considered in the interest of the patient's health (as defined for the respective test procedure). [Note: This level is situated between 'H' and 'HH'.]
HH	Above upper panic limits	The result for a quantitative observation is above a reference level at which immediate action should be considered for patient safety (as defined for the respective test procedure). Synonym: Above upper panic limits

Interpretations across results over time assessment of including patient condition

Code	Concept Name	Definition
B	Better--use when direction not relevant	The current result or observation value has improved compared to the previous result or observation value (the change is significant as defined in the respective test procedure). [Note: This can be applied to quantitative or qualitative observations.]
W	Worse--use when direction not relevant	The current result or observation value has degraded compared to the previous result or observation value (the change is significant as defined in the respective test procedure). [Note: This can be applied to quantitative or qualitative observations.]

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Interpretations across numeric results over time

Code	Concept Name	Definition
D	Significant change down	The current result has decreased from the previous result for a quantitative observation (the change is significant as defined in the respective test procedure).
U	Significant change up	The current result has increased from the previous result for a quantitative observation (the change is significant as defined in the respective test procedure).

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Interpretations of results in relation to reference ranges, typically for non-numeric observations

Code	Concept Name	Definition
A	Abnormal (applies to non-numeric results)	The result or observation value is outside the reference range or expected norm (as defined for the respective test procedure). [Note: Typically applies to non-numeric results.]
AA	Very abnormal (applies to non-numeric units, analogous to panic limits for numeric units)	The result or observation value is outside a reference range or expected norm at a level at which immediate action should be considered for patient safety (as defined for the respective test procedure). [Note: Typically applies to non-numeric results. Analogous to critical/panic limits for numeric results.]

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Interpretations of results without indication to normal ranges

Code	Concept Name	Defintion
DET	Detected	The measurement of ~~a given~~ the specified component / analyte, organism or clinical sign ~~substance~~ above the limit of detection of the performed test or procedure. ~~of the assay.~~
POS	Positive	A presence finding of the specified ~~given~~ component / analyte, organism or clinical sign ~~substance~~ based on the established ~~signal~~ threshold ~~or cut-off signal level~~ of the performed test or procedure.
IND	Indeterminate	~~Indicating t~~The specified ~~a given~~ component / analyte, organism or clinical sign ~~the analyte tested for~~ could neither be declared positive / negative or detected / not detected by the performed test or procedure.
ND	Not Detected	The presence of the specified component / analyte, organism or clinical sign ~~A given substance~~ could not be determined ~~measured~~ within the limit of detection of the ~~assay~~ performed test or procedure.
NEG	Negative	An absence finding of the specified ~~a given~~ component / analyte, organism or clinical sign ~~substance~~ based on the established ~~signal~~ threshold ~~or cut-off signal level~~ of the performed test or procedure. [Note: Negative does not necessarily imply the complete absence of the ~~substance~~specified item.]
RR	Reactive	A presence finding used to indicate that the specified component / analyte ~~tested for~~ reacted with the reagent above the reliably measurable limit of the performed test.
WR	Weakly reactive	A weighted presence finding used to indicate that the specified component / analyte ~~tested for~~ reacted with the reagent, but below the reliably measurable limit of the performed test.

Information about why test result was not obtained

Code	Concept Name	Defintion
AC	Anti-complementary substances present	A valid result cannot be obtained for the specified component / analyte due to the presence of anti-complementary substances in the sample.
QCF	Quality Control Failure	A result cannot be considered valid for the specified component / analyte or organism due to failure in the quality control testing component.
TOX	Cytotoxic substance present	A valid result cannot be obtained for the specified organism or cell line due to the presence of cytotoxic substances in the sample or culture.

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Interpretation of a genetic test result

Code	Concept Name	Defintion
CAR	Carrier	The patient is considered as a carrier based on the testing results. A carrier is an individual who carries an altered form of a gene which can lead to having a child or offspring in future generations with a genetic disorder.

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Exclusion criteria for study participation

Code	Concept Name	Defintion
EX	Outside threshold	The observation/test result is interpreted as being outside the inclusion range for a particular protocol within which the result is being reported. Example: A positive result on a Hepatitis screening test. [Note: THIS IS INTENDED FOR USE IN CLINICAL TRIALS ONLY]
HX	Above high threshold	The numeric observation/test result is interpreted as being above the high threshold value for a particular protocol within which the result is being reported. Example: An ALT (SGOT) result above a protocol-defined threshold value of 2.5 times the upper limit of normal based on the subject's sex and age. [Note: THIS IS USED IN CLINICAL TRIALS ONLY!]
LX	Below low threshold	The numeric observation/test result is interpreted as being below the low threshold value for a particular protocol within which the result is being reported. Example: A Total White Blood Cell Count falling below a protocol-defined threshold value of 3000/mm^3 [Note: THIS IS USED IN CLINICAL TRIALS ONLY!]