

ARUP is an enterprise of the University of Utah and its Department of Pathology.

Charting reference intervals and flagging abnormal results

Components of a laboratory test result

A laboratory test result issued by ARUP or most any other clinical laboratory in the U.S. has several components:

- The result itself, which may be a number (numeric) or words (alphanumeric)
- A reference interval as applicable
- A *Flag* as applicable. Available flags include *H* (high), *L* (low), *A* (abnormal), and *C* (critical)
- Additional interpretive comments and/or footnotes as applicable.

Establishing reference intervals

To assist physicians and other care providers interpret test results, ARUP provides reference values when available for tests. The original concept of a reference interval (formerly referred to as a *normal range*) was the central 95% of results from a healthy volunteer population. Such an interval divides results into *low*, *normal* and *high*. Some tests, such as serum sodium, use this form of reference interval. Other tests, however, use reference intervals based on the expected values in different disease states, and some have multiple gradations of normal and abnormal.

ARUP uses the Cerner Millennium Pathnet laboratory information system (LIS) to manage test results. Like most other laboratory information systems, Millennium Pathnet functions simplistically; it does not allow multiple gradations in reference interval reporting, such as would distinguish equivocal from positive results.

For tests such as serum sodium for which the traditional form of the reference interval is applicable, ARUP uses the Millennium Pathnet reference interval function. The reference interval automatically appears next to the test result in ARUP's System 2000 and paper chart formats. The reference interval will also be passed across HL7 interfaces into client lab information systems, which will likewise allow similar charting functions.

For many tests, however, the use of a traditional reference interval would oversimplify the test results and mislead physicians and other care providers (see examples below). In such cases, ARUP's medical directors often choose to present interpretive information in the form of a textual footnote comment attached to the result rather than rely on the reference interval function in our LIS.

Mechanisms for setting high/low flags

When a test has been set up in our LIS with a result type of *numeric*, and if a reference interval has been defined in the LIS for that test, then the high/low flags will automatically appear for each test result based on that reference interval. A *numeric* result that is greater than the upper end of the reference interval will automatically flag as *H* and a *numeric* result that is less than the lower end will automatically flag as *L*.

Tests with a result type of *numeric*, for which no reference interval is defined in the LIS do not trigger any flags regardless of the result (see examples below). Tests set up with a result type of *alphanumeric* are flagged according to rules defined in the LIS by ARUP. For example, ARUP might flag a test result of positive as either high or abnormal.

Complexities in flagging test results

Use of a single reference interval which categorizes results as *high*, *low* or *abnormal* works well for tests such as serum sodium where the interpretation is best made in comparison to results in a healthy population. However, for other tests, especially highly esoteric ones, the traditional concepts of *high*, *low* or *abnormal* and

even *reference interval* do not apply cleanly, and flagging results in this fashion can be misleading.

The following examples demonstrate the over-simplification and misinformation that could occur if traditional reference intervals were used:

Equivocal test results for West Nile Virus IgG

West Nile Virus IgG, like most other infectious serology tests, has three result categories: a numeric result of <1.3 is negative, a result of 1.3 to 1.5 is equivocal, and >1.5 is positive. An *H* flag would be assigned for results >1.5; and an *L* flag for results <1.3. No mechanism exists for defining an *equivocal* range inside or alongside a reference interval. For these reasons ARUP's immunology laboratory has historically chosen to not define a reference interval in the LIS for these tests; instead they provide interpretive information in a comment that accompanies each test result.

Positive test results for Measles IgG

For measles IgG, at least two plausible clinical scenarios exist which have very different charting implications. Determining whether to flag a positive result as normal or abnormal is not straightforward. For an unvaccinated child, a positive result would be clearly abnormal, and it might seem reasonable to flag such a result as *high*. The same result on a vaccinated child, however, would be considered normal, and a *high* flag would be misleading. Conversely, in a vaccinated child, a negative test is usually abnormal and reflects a need for a booster vaccination, and so it would seem reasonable to have it trigger a *low* flag. But in an unvaccinated child with a history of viral rash, this would simply be a negative result.

Compliant or illicit use of Opiates

Opiate testing is ordered in two major clinical settings, both of which are very common in pain clinics. For patients who have been prescribed opiates, the test is used to verify that the patient is taking the drug and thus presumably not diverting the drug into the black market. For such patients it would seem reasonable to flag negative results as *low* and not flag positive results. On the other hand, for patients not prescribed opiates, the test is used to detect illicit opiate use. In this setting, it would seem reasonable to flag positive results as *high* and not flag negative results.

Limitations of charting systems

Many ARUP client laboratories issue laboratory results to their physicians in the form of paper charts. A few of these charting systems display the results in the form of *Normal* and *Abnormal* columns. In order to determine in which column to place a result, these systems typically look for the presence of a flag (*H*, *L*, *C* or *A*); all flagged results display in the abnormal column, and everything else in the normal column.

Knowing whether a result is normal or abnormal for a given patient depends on clinical context; making that designation on a chart based simply on the existence of a flag or footnote is simplistic and at times misleading to the clinician. It is critical that physicians review all test results, not just the ones that a laboratory has labeled as abnormal. As illustrated in the examples above, it is not always possible for ARUP Laboratories to define reference ranges and flag settings in our LIS in ways that satisfy all the major clinical settings in which a test is used. ARUP does not recommend the practice of charting results in *Normal* and *Abnormal* columns.

Oversight for charting test results at ARUP

ARUP medical directors set and review the reference intervals, flagging rules and interpretive comments for the various tests performed in their laboratories. Reviews occur regularly in keeping with the College of American Pathologists Laboratory Accreditation Program. ARUP also has a Charting Committee which provides an additional level of oversight for charting issues.

ARUP appreciates feedback from laboratory managers and pathologists at its client sites regarding charting. However, we cannot customize most aspects of charting to fit local client preference. The guiding principle in all charting decisions is the optimal support of patient care.