Clinicians have asked about analyte-specific reagents (ASRs) and the implications around their use. About a year ago, our Clinical Virology Laboratory introduced a new test for herpes simplex virus (HSV) DNA that uses a PCR-based assay. With each result, a comment called an “ASR notice” is appended that reads: "Analyte-Specific Reagents are used in many laboratory tests necessary for standard medical care and generally do not require U.S. Food and Drug Administration (FDA) approval. This test was developed, and its performance characteristics determined by Fairview Laboratory Services. It has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research."

This notice is required by federal law whenever a clinical laboratory uses ASRs in a test used for patient care. Using ASRs is allowed, but the disclaimer must appear with every reported result.

The FDA defines an ASR assay as "antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens." (ref: 21 CFR 864.4020[a]).

Read more about who can use ASRs and how their accuracy is validated.

Effective March 1, red blood cell counts on body fluids—with the exception of CSF—will no longer be reported. The laboratory will continue to report the appearance of the fluid (bloody, slightly bloody, colorless, etc), which is usually more than clinically adequate. Red blood cell counts will continue to be reported on all cerebrospinal fluids, as well as white blood cell counts on all fluids.

Effective Feb. 15, the Clinical Microbiology Laboratory at University of Minnesota Medical Center, Fairview will not routinely perform both Clostridium difficile PCR and culture on fecal specimens. The PCR is the test of choice, based on our internal comparisons of the two assays, and it is what is used by some major laboratories with our overall expertise.

The PCR assay tests for toxin B, considered the major virulence factor for C. difficile. If the PCR assay results in an invalid result due to interfering substances or for other reasons, we will reflex to the anaerobic culture for C. difficile. Health care staff may still order the culture, but this will not be the lab's routine.

A patient with clinical illness suggesting C. difficile with negative tests for other causes and a negative PCR for C. difficile toxin B might be an example for considering the C. difficile culture.

Fairview Laboratories have converted to the Ortho Clinical Diagnostics' colorimetric reflectance spectrophotometry methodology for measuring fluid bilirubin quantitatively. The test is performed in the University Acute Care Laboratory and provides 24/7 availability. All other Fairview sites will discontinue fluid
bilirubin testing by Ictotest® and send specimens to the University Acute Care Lab for quantitative analysis due to low test volumes.

Fluid bilirubin testing has historically been performed as a qualitative assay by Ictotest. Periodically, the laboratories have received requests from physicians to report the quantitative bilirubin on fluid samples. The quantitative result has been entered as a comment with the qualitative result. Now that all fluid bilirubins are being reported quantitatively, the qualitative test will be discontinued.

**Multi-method fluid bilirubin comparison**

Fluid bilirubin samples were tested by Ictotest (qualitative), Aution 10TA Strip® (visual semi-quantitative chemical dipstick) and Vitros (quantitative total bilirubin) methodologies. The quantitative linear range is 0.1-27.0 mg/dL. Samples above the linear range will be diluted.

- Specimen requirements: 1 mL specimen collected in a plastic leakproof container
- Alternate: green blood tube (lithium heparin, gel); red blood tube (no gel); red or gold blood tube (gel)

**Reference/therapeutic range**

The result will be reported with the coded comment: "No reference ranges have been established. This result should be interpreted in the context of the patient's clinical condition and compared to simultaneous measurement in the patient's blood."

Test-specific information is available in the [Lab Guide](#).

If you have questions, contact [John Eckfeldt](#), MD, medical director, Acute Care laboratory, 612-626-3176; or [Julie Jacobs](#), technical supervisor, University Acute Care Laboratory, 612-273-0149.