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Patient demographics: A vital role in prenatal screening

Prenatal screening — and first-trimester screening in particular — are highly effective means for identifying fetuses that may be at risk of chromosomal and other abnormalities, signaling the need for additional testing. First-trimester screening provides earlier information about potential complications for the fetus.

To obtain the most accurate results, however, the lab must receive not just a serum specimen but also the most complete patient demographic data possible. Danelle Beaudoin, Ph.D., Legacy Laboratory Services' scientific director of chemistry, explains:

“The first-trimester screen isn't as simple as measuring blood glucose,” she says. “We need to have a great deal of demographic information about the patient in order to produce the most accurate risk assessment. Incomplete or inaccurate information may lead to both false-negative and false-positive screens.”

This demographic information includes the mother's date of birth, ethnicity, weight, estimated date of delivery (EDD), number of fetuses, whether she was medication-dependent diabetic or a smoker at conception, if this is an IVF pregnancy, and if the mother has had a previous pregnancy with a chromosomal abnormality.

Why is information like age, ethnicity or weight so crucial?

“As a woman ages, her *a priori* risk for Down syndrome increases,” Dr. Beaudoin explains. “As for race, certain blood serum values are

higher in African-American women than in Caucasian women, and birth prevalence of neural tube defects is 50 percent lower in African-Americans than Caucasians, so it's important to adjust for race differences before assessing risk.

“As weight decreases, concentrations of certain serum markers increase,” she continues. “Conversely, as weight increases, these serum marker concentrations decrease. These changes may lead to false-positive and -negative results, especially for trisomy 18 and neural tube defects.”

To more fully explain the reasons referrers are asked for this level of patient detail on its screening requisition form, Legacy Laboratory Services has prepared a comprehensive but

easy-to-read document, *Importance of Patient Demographics to Assessing Risk*, available at tinyurl.com/LegacyLab-collectionguidelines.

Another critical element of the first trimester screen is ultrasound,

which is combined with blood test results to give one interpretation.

“To ensure the greatest accuracy, Legacy only accepts results from sonographers who have been trained by either the Fetal Medicine Foundation or the Nuchal Translucency Quality Review Program,” Dr. Beaudoin notes. “Each sonographer should be set up with our prenatal screening program before a patient's blood work is referred to the lab.

“It's best to allow one week before submitting patient specimens to give us time to set up new

For the most accurate results with first-trimester screening, the lab must have the serum specimen and also the most complete patient demographic data possible.



Prenatal screening: Detailed information crucial for accurate results

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sonographer parameters in our system,” she adds.

“While it may seem overwhelming to provide all this information, it really is crucial for getting an accurate result,” Dr. Beaudoin stresses, “and we strive to deliver consistently accurate results.”

In fact, Legacy Laboratory Services is one of only two labs in the entire state to even perform first trimester screens.

“Fewer facilities are doing these tests in-house because of the level of patient detail required to get accurate results — and the liability involved if they’re not accurate,” she explains. “We take a lot of pride in our quality assurance, and go above and beyond what’s required by the accrediting agencies we subscribe to.

“It’s also why we require the most complete patient demographic information possible for prenatal

screening,” she adds. “Parents-to-be deserve the most accurate assessment of whether their fetus is at risk of chromosomal abnormalities so they can make an informed decision about next steps.”

Dr. Beaudoin also points out that relying on Legacy’s local laboratory services is also a plus when time is a factor.

“By using a local reference lab, you can get results at least one day faster since you don’t have the extra travel time involved in getting specimens to the lab in a different state,” she says. “In prenatal screening, this can be quite important if additional procedures need to be performed based on the screening result.”

To learn more about prenatal screening at Legacy Laboratory Services, read our FAQs on page 3 and visit the collections guidelines for prenatal screening on the Legacy Laboratory Services website at tinyurl.com/LegacyLab-collectionguidelines.

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ICD-10: Code to highest degree of specificity

As of Oct. 1, the grace period restricting ICD-10 specificity-related denials ended. This opened the door for payors to deny coverage for “not otherwise specified” (NOS) or “unspecified” codes appended to lab orders even though the medical record contains documentation that would allow for proper coding to the highest degree of specificity. This is also the date the updated 2017 ICD-10 Code Set became effective, with more than 3,650 new codes (mostly in the cardiovascular system section) and more than 730 revisions.

Legacy Laboratory Services and Cascade Pathology contract with major insurers

Legacy Laboratory Services (LLS) and Cascade Pathology contract with major insurance providers including Blue Cross, Aetna, Cigna, and United HealthCare. From time to time, communications from insurers will feature one national lab or another citing savings for patients. These commu-

nications, meant for broad distribution, downplay the vital role of local partners. As local and regional preferred providers, LLS and Cascade Pathology are proud to offer not only competitive out-of-pocket costs for insured and uninsured patients, but the true value that comes from community-based commitment to quality care and convenient service options.

For additional information, please consult your account services representative. A list of insurer contracts is available on our website.

Syphilis: New screen and testing algorithms

Due to increased requests for syphilis screening and patient monitoring, Legacy Laboratory Services has adopted an automated chemiluminescent immunoassay (CIA) as the initial syphilis screen. A Legacy LabAlert is available on our website describing screening and monitoring options. To download it, visit <http://tinyurl.com/SyphilisLabAlertPDF>.

First trimester screening Frequently Asked Questions

What is the gestational age window for first trimester testing?

Specimen must be drawn in the first trimester between 11 weeks, 0 days, and 13 weeks, 6 days. (Crown-Rump length (CRL) must be between 40.6 and 84.0 mm). CRL and NT have to be measured at the same time. Patient history information is required.

What are the specific parameters for FTS?

PAPP-A, hCG, NT and patient demographics

How do we set up our sonographer(s) to send measurements?

- a. A copy of the certificate from either Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR) (or certification number and certifying agency) is required for each sonographer.
- b. Complete Legacy Laboratory Services' (LLS) Sonographer Nuchal Translucency (NT) Thickness and Crown-Rump Length (CRL) data entry form

- c. Clinic/client will be informed when LLS is ready to accept measurements.

Does Legacy monitor the sonographers?

Yes. Sonographer is responsible for maintaining current certification with FMF or NTQR agencies. Legacy evaluates sonographers in-house, but also submits NT and CRL measurements to certification agencies at the requested intervals.

How does Legacy handle the sonographers who do not measure the same as the rest of the sonographers in the clinic?

The sonographer is given their own equation since he or she will skew the group equation.

What is the risk cutoff for Down syndrome (trisomy 21)?

1:230

What is the risk cutoff for trisomy 18?

1:100

How are recalculations requested?

Contact the registrar of LLS Prenatal Screening Program at 503-413-5133

QIAGEN, LLS partner to develop genetic testing instrumentation

QIAGEN, a long-time contributor of molecular diagnostic testing, has recently launched a new next-generation sequencing (NGS) platform that combines DNA extraction, library preparation, sequencing and bioinformatics pipeline into one workflow to uncover actionable variants in the most common solid tumors that affect our patients.

More importantly, and based on the expertise of our team in the Molecular Diagnostic department, QIAGEN has chosen Legacy Laboratory Services as a partner and beta site to validate its new platform. This opportunity has allowed our team to test a cohesive workflow from patient specimen to



Peer Schatz (left), CEO of Qiagen, with Yasmine Akkari and Don Toussaint of Legacy Laboratory Services

an actionable report, in an effort to bring this state of the art clinical molecular testing to the Legacy genetics laboratory.



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