



April 21, 2008

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TECHNICAL BULLETIN

NEW TEST ANNOUNCEMENT

Quadruple Marker Testing (Quad Screen) By ELISA (immunoassay)

The search for serum biomarkers to improve the sensitivity for second trimester Down's syndrome screening led to the study of inhibin A, a protein produced by the syncytiotrophoblast of human placental tissue. Inhibin A acts on the pituitary gland to inhibit follicle stimulating hormone synthesis and secretion, shutting down the menstrual cycle during pregnancy. Studies in the early 1990s suggested that inhibin A in second trimester maternal serum were elevated in about half of the pregnancies affected by Down's syndrome.

The triple screen profile, consisting of alpha-fetoprotein, human chorionic gonadotropin and unconjugated estriol have been used in conjunction with maternal age since the early 1990s as screening tests for fetal Down's syndrome. Typically analyzed at 16-18 weeks of gestation, this multiple marker maternal serum screen demonstrated about a 60% Down's syndrome detection rate of all affected pregnancies. All assay numeric results are compared to a cumulative mean for a given gestational age to determine a multiple of the mean (MoM). The MoMs for the three assays were then combined in a complex algorithm to determine the probability of Down's syndrome.

Studies have shown that the addition of inhibin A to the triple marker screen into a quadruple marker screen, increases the detection rate of Down's syndrome in second trimester screening to 75-81% of all affected pregnancies. Quad marker testing also enhances the specificity of the screening by detecting fewer false positive cases than the triple marker screen. Consequently, we will be offering the quadruple marker screen only and will no longer offer a triple marker screen.

Please see back page for further information or contact any of our client services representatives:

Oahu	677-7998
Hawaii	961-5812
Kona	322-4126
Kauai	245-7775
Maui	244-5567

(Over for more information)

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NEW TEST INFORMATION

Quadruple Marker Testing (Quad Screen) By ELISA (immunoassay)

Specimen Requirements	<i>0.5 mL serum or plasma. Hemolyzed or lipemic samples cannot be assayed. Avoid repeated freezing and thawing of specimens</i>
Specimen Stability	<i>Ambient: Not assessed Refrigerated: 24 hours Frozen (-20°C): 30 days</i>
Effective Date	<i>May 12, 2008</i>
Testing Site	<i>Hawaii Medical Center – West Core Laboratory</i>
Reference Ranges	<i>Down Syndrome: $\geq 1:270$ Trisomy 18: $\geq 1:100$ Neural Tube defects: MoM ≥ 2.5</i>
Testing Schedule	<i>Sundays, Tuesdays and Thursdays</i>

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