

SEQUENTIAL MATERNAL SCREEN
#60698 PART 1 – 1ST TRIMESTER
#60700 PART 2 – 2ND TRIMESTER

EXPLANATION: Mayo Medical Laboratories is pleased to announce the availability of our Sequential Maternal Screen.

**** IMPORTANT NOTE** Approval to send samples for Sequential Maternal Screening is required and may take up to 5 business days to complete.**

TESTING ALGORITHM:

Sequential Maternal Screen is a two-part test with first- and second-trimester components. It requires a Nuchal Translucency (NT) measurement and blood draw in the first trimester (Part 1 #60698). If the result from Part 1 indicates a risk for Down syndrome that is higher than the screen cutoff, the screen is completed and a report is issued. If Part 1 results are negative, an additional blood draw in the second trimester is required (Part 2 #60700). Information from Part 1 is combined with Part 2 to determine a risk for Down syndrome and Trisomy 18. An assessment for Neural Tube Defects is also provided. If the second specimen is not received for sequential screening, the results will be reported as uninterpretable with no risk provided.

PROFILE INFORMATION:

SEQUENTIAL MATERNAL SCREEN, PART 1 PROFILE INFORMATION:

Unit Code	Reporting Name	Available Separately	Always Performed
29451	Maternal Information	No	Yes
29468	PAPP-A	No	Yes
29469	Results and Interpretation	No	No

SEQUENTIAL MATERNAL SCREEN, PART 2 PROFILE INFORMATION:

Unit Code	Reporting Name	Available Separately	Always Performed
29476	Maternal Information	No	Yes
29494	AFP	Yes (order #81169 for Neural Tube Defect, #8162 for Serum Tumor Marker, #8876 for Spinal Fluid Tumor Marker)	Yes
29495	uE3	Yes (# 81711)	Yes

Unit Code	Reporting Name	Available Separately	Always Performed
29496	hCG, Total	Yes (order #80678 for Pregnancy Test, #8693 for Serum Tumor Marker, #8877 for Spinal Fluid Tumor Marker)	Yes
29497	Inhibin A	Yes (order #81049 for Inhibin A Tumor Marker)	Yes
29499	Summary of Screen Risks	No	Yes
29503	Interpretation	No	Yes
29505	Recommended Follow-Up	No	Yes
29506	General Test Information	No	Yes

USEFUL FOR: Prenatal screening for:

- Down syndrome: NT and PAPP-A in first trimester; and AFP, Unconjugated Estriol (uE3), Human Chorionic Gonadotropin (hCG), and Inhibin A in second trimester.
- Trisomy 18: NT and PAPP-A in first trimester; and AFP, hCG, and uE3 in second trimester.

METHODOLOGY: Two-Site Immunoenzymatic (Sandwich) Assays

REFERENCE VALUES:

DOWN SYNDROME:

Part 1: (first trimester):

Calculated screen risks of $<1/50$ for Down syndrome are considered screen negative and will not be reported after the first trimester component. A second specimen in the second trimester will be requested to complete the sequential screen.

Risks $\geq 1/50$ for Down syndrome are reported as screen-positive in Part 1.

Part 2: (first and second trimester):

Risks $\geq 1/270$ for Down syndrome are reported as screen-positive in Part 2.

TRISOMY 18:

Part 1 and 2:

Calculated screen risks $<1/100$ are reported as screen-negative.

Risks $\geq 1/100$ are reported as screen-positive.

A numeric risk for Trisomy 18 risk is provided with positive results.

NEURAL TUBE DEFECTS:

An AFP multiple of the median (MoM) of ≥ 2.5 is reported as screen positive (Part 2 only).

SPECIMEN REQUIREMENTS: Nuchal Translucency (NT) measurements are only accepted from NT-certified sonographers. *Do not send samples to Mayo if the sonographer is not NT-certified or before completing the application process.*

The link below will direct you to the getting started site:

<http://www.mayomedicallaboratories.com/customer-service/forms/maternal-screening.html>

Draw blood in a plain, red-top tube(s) or a serum gel tube(s). Spin down immediately and send 1.0 mL of maternal serum refrigerated. Collect one specimen in the first trimester between 10 weeks, 0 days and 13 weeks, 6 days (which corresponds to a crown-rump length (CRL) range of 31 mm to 80 mm) and send with demographic/pregnancy information (see note below). Collect one specimen in the second trimester between 15 weeks, 0 days and 22 weeks, 6 days and send (no demographic/pregnancy information required).

Note: The following information is required for processing Part 1 of Sequential Maternal Screen.

- A. Physician name and phone number
- B. Serum collection date
- C. Date of birth (not age)
- D. Weight (indicate lbs or kg)
- E. Is patient an insulin-dependent diabetic? (select *Yes* if patient on insulin prior to this pregnancy; otherwise, select *No*)
- F. Race (select **Black** or **Other/Non-Black/Mixed**)
- G. Is this an in-vitro fertilization pregnancy?
 - If donor egg used, please specify **egg** donor's date of birth (or, if unknown, current age)
 - If frozen egg or embryo used, how long was egg or embryo frozen?
- H. Has this patient had a previous pregnancy with Down syndrome (Trisomy 21) or other Trisomy?
- I. Sonographer name
- J. Sonographer code (assigned by Mayo)
- K. Ultrasound date
- L. Crown-Rump Length (CRL). The CRL measurement must be between 31 mm and 80 mm, which corresponds to gestational dating between 10,0 (weeks,days) and 13,6 (weeks,days). If the blood specimen is drawn outside of this gestational window, we will not be able to calculate risks.
- M. Nuchal Translucency measurement (mm)
- N. Is this a twin pregnancy? If yes, please provide CRL and NT for each twin. Note: *risk estimates are not available for 3 or more fetuses.*
- O. Please submit a completed First-Trimester/Sequential Screening form (T593) with each sample. These forms are available online (or through Mayo Medical Laboratories (1-800-533-1710)).

CAUTIONS:

- Upon receiving maternal serum screening results, all information used in the risk calculation should be reviewed for accuracy (e.g., maternal date of birth, demographics, sonographic information). If any information is incorrect, the laboratory should be contacted for a recalculation of the estimated risks.
- The use of these markers to screen for Down syndrome or Trisomy 18 is not an approved Food and Drug Administration (FDA) procedure.

- Variables Affecting Marker Levels:
 - o All serum marker multiple of medians (MoMs) are adjusted for maternal weight (to account for dilution effects in heavier mothers). The estimated risk calculations and screen results are dependent on accurate information for gestation, maternal age, and weight. Inaccurate information can lead to significant alterations in the estimated risk.
- A screen-negative result does not guarantee the absence of fetal defects. A screen-positive result does not provide a diagnosis, but indicates that further diagnostic testing should be considered (an unaffected fetus may have screen-positive result for unknown reasons). In fact, given the low prevalence of Down syndrome, the majority of women with a positive screen will not have a fetus with Down syndrome.
- In affected twin pregnancies, the distribution of analyte markers is largely unknown and the contribution of each analyte by each twin cannot be discerned. Consequently, the risk for Down syndrome is approximated, using twin-adjusted medians. A specific risk for Trisomy 18 cannot be approximated; therefore, results are reported as either screen-negative or screen-positive. Risks for triplets and higher order pregnancies cannot be calculated.
- Each center offering maternal serum screening to patients should establish a standard screening protocol, which provides pre- and post-screening education and appropriate follow-up for screen-positive results.
- NT measurements must be obtained from a trained and certified sonographer. NT quality indicators will be monitored on a regular basis. Institutions will be contacted if there is ongoing deviation in the quality indicators.

LIST FEE: #60698 PART 1 - \$125.14
#60700 PART 2 - \$179.87

CPT CODE: 84163/Pregnancy-associated Plasma Protein-A (PAPP-A)
84702/Gonadotropin, Chorionic (hCG); Quantitative
82105/AFP
82677/Estriol, Unconjugated (uE3)
86336/Inhibin A

ANALYTIC TIME: Same day/1 day

DAY(S) SET UP: Monday through Friday 5 a.m.-12 a.m.,
Saturday 6 a.m.-6 p.m.

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager
Greg Renkly, Mayo Medical Laboratories' Technologist Support
Telephone: 800-533-1710