

Client Request to Change Maternal Serum Screening Down Syndrome Cut-Off

Client Number(s) _____

Name of Hospital, Lab, or Medical Group _____

Printed Name _____ Phone Number _____

The purpose of maternal serum screening (MSS) testing is to identify fetuses at increased risk of being affected with Down syndrome, trisomy 18, or an open neural tube defect. These tests are designed for screening and are not diagnostic tests. As such, false-positive test results are common, and the tests fail to identify some affected fetuses. MSS tests utilize biochemical and, in some cases, ultrasound measurements to determine the risk that a fetus will be affected with any of the aforementioned disorders.

The detection rate (DR) is the percentage of affected fetuses that are correctly identified by the screening test. The screen positive rate (SPR) is the percentage of all test results that are interpreted as positive (abnormal). The two rates are strongly affected by maternal age and the risk cut-off used to determine a positive test result. Altering the risk cut-off has only a slight effect on the detection rate because the affected fetuses represent a minor portion of the total population screened. In contrast, changes to the risk cut-off have a profound impact on the screen positive rate because the SPR is based on the entire screened population. The effects of changes to the risk cut-off are more easily appreciated by comparing the odds of being affected given a positive result (OAPR) for each risk cut-off. For example, assume that 70,000 pregnancies are screened using the quad test. A population this large will produce approximately 100 Down syndrome cases. Using a cut-off of 1 in 150 will classify 3,010 patients as abnormal; following workup, 81 actual cases of Down syndrome will be identified. Alternatively, using a 1 in 270 cut-off will classify 4,690 patients as abnormal and would detect only 4 additional affected pregnancies. The OAPR using 1 in 150 is 1 in 29, while the OAPR using 1 in 270 is 1 in 44. Thus, using 1 in 270 as a cut-off requires that 15 more women get worked up to find each additional case of Down syndrome compared to using a cut-off of 1 in 150.

ARUP Laboratories is committed to providing excellent patient care. Because each positive test result, whether correct or not, has a downstream cost associated with it (both fiscal for the healthcare system and emotional for the patient), ARUP has chosen default cut-offs for each screen that maximize detection while maintaining a screen positive rate of 5 percent or less. We strive to work in partnership with healthcare providers to provide MSS test interpretations consistent with their philosophies. Therefore, ARUP offers clients a choice in Down syndrome screening cut-offs.

Please examine the DR, SPR, and OAPR provided for each MSS test below. You have the option of using the default ARUP cut-off, a cut-off of 1 in 270, or a cut-off of your choice. Please check in the space provided to choose your desired cutoff for each MSS test. If a test cut-off is not selected, the default ARUP cut-off will be used for that test.

Quad test: Alpha-fetoprotein (AFP), human chorionic gonadotropin (hCG), unconjugated estriol (uE3), and dimeric inhibin A (DIA)		
DS cut-off	ARUP default 1 in 150	Alternative 1 in 270
DR	81%	85%
SPR	4.3%	6.7%
OAPR	1 in 29	1 in 44
Selection	<input type="checkbox"/> Use the default cut-off of 1 in 150	<input type="checkbox"/> Change cut-off to 1 in 270
	<input type="checkbox"/> Use the following cut-off of our choice: 1 in _____	

First-trimester only test: Pregnancy-associated plasma protein-A (PAPP-A), total hCG, and fetal nuchal translucency (NT)		
DS cut-off	ARUP default 1 in 230	Alternative 1 in 270
DR	83%	85%
SPR	7.4%	8.5%
OAPR	1 in 20	1 in 24
Selection	<input type="checkbox"/> Use the default cut-off of 1 in 230	<input type="checkbox"/> Change cut-off to 1 in 270
	<input type="checkbox"/> Use the following cut-off of our choice: 1 in _____	

Integrated Test: PAPP-A, AFP, hCG, uE3, DIA, and optional NT, with a single interpretation after both samples are tested.		
DS cut-off	ARUP default 1 in 110	Alternative 1 in 270
DR	88%	93%
SPR	4.9%	8.5%
OAPR	1 in 13	1 in 22
Sequential Test: PAPP-A, NT, AFP, hCG, uE3, and DIA, interpretation performed after each sample is tested.		
DS cut-off	ARUP default 1 st 1 in 25 2 nd 1 in 110	Alternative 1 st 1 in 25 2 nd 2 in 270
DR	92%	94%
SPR	5.5%	8.3%
OAPR	1 in 14	1 in 21
Integrated and Sequential tests Selection*	<input type="checkbox"/> Use the default cut-off of 1 in 110	<input type="checkbox"/> Change cut-off to 1 in 270
	<input type="checkbox"/> Use the following cut-off of our choice: 1 in _____	

**Sequential-2 and Integrated tests are required to have the same cut-off*

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I, (the above named) certify that I am authorized on behalf of (named hospital, lab, medical group) to make the above choices. I understand that these choices will apply to all specimens collected after this agreement goes into effect. An ARUP representative will contact me with an effective date once this paperwork has been received and processed. Any specimens collected prior to the effective date, even if recalculated after the effective date, will not be affected by this agreement. I also certify that I understand that the above changes will be made for all maternal serum screening specimens received by ARUP under the above listed client numbers.

It is my responsibility to ensure that all applicable client numbers used by the above-named hospital, lab, or medical group are listed above. It is also my responsibility to notify an ARUP genetic counselor at (800) 242-2787, ext. 2141, if a new client number is added so that the same cut-off values can be applied to any testing performed under that new client number. I may modify the Down syndrome cut-off values requested above by contacting a genetic counselor at the above number.

Signature

Date