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August 2010

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Changes in Maternal Serum Screen Tests

Maternal Serum Screening tests are very useful to help identify pregnancies of increased risk for Down syndrome (DS), Trisomy 18 (T18), or open neural tube defects (ONTD) such as spina bifida. The intent of these screening tests is to enable pregnant women to make informed decisions regarding the pregnancy and be better prepared in the event of the birth of an affected infant.

Down syndrome is the most common chromosome abnormality among live births and the most frequent form of intellectual disability caused by a demonstrable chromosomal aberration. It arises from the presence of an extra copy of chromosome 21 in the cells of the fetus. Mental retardation, characteristic features of the face and medical problems such as heart defects occur as a result of this extra chromosome 21. About 40% of pregnancies with Down syndrome will miscarry between 11 weeks and term, but 9 out of 10 affected babies who reach term will survive the first year and about one half of these individuals will reach 60 years of age. The syndrome is characterized by moderate to severe learning disability (average IQ approximately 40) in combination with short stature, characteristic facial features, heart defects (40 to 50% of cases), intestinal malformations (10% of cases), problems with vision and hearing (50% of cases), an increased frequency of infection, and other health problems.



Photo: Kevin Vance

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Maternal age alone was the initial risk factor used for screening pregnancies for Down syndrome. The risk of giving birth to a baby with Down syndrome as a function of maternal age is nonlinear and ranges from approximately 1 in 1500 in young women to 1 in 10 in a 48-year-old. The risk is almost constant at ages 15 to 25, rises slowly between ages 25 to 35, and then increases approximately four-fold from ages 35 to 40 and 10-fold from ages 40 to 45; there are data that suggest the risk of Down syndrome does not increase further beyond age 45.

T18 is a rare (birth prevalence about 1 in 7000) and usually fatal abnormality which arises from an extra copy of chromosome #18 in the cells of the fetus. The prevalence is 3-5 fold higher in the first and second trimesters than at birth because many affected fetuses die in utero with advancing gestation. Trisomy-18 causes severe mental retardation and birth defects. Only 10% of live borns with this condition will reach one year of age.

ONTD's are congenital structural abnormalities of the brain (Anencephaly) and vertebral column (spina bifida) that occur either as an isolated malformation, along with other malformations, or as part of a genetic syndrome. The cause of non-syndromic ONTD's is not known. Scientists believe that genetic, environmental and nutritional components all play an important role. ONTD's occur in 1-2 per 1000 pregnancies and are the second most common major congenital anomaly worldwide. Anencephaly accounts for one half of all cases of ONTD and is incompatible with life. With treatment, 80-90% of infants with Spina Bifida survive with varying degrees of disability. Most importantly, ONTD's are among the few birth defects for which primary prevention is possible (ACOG Practice bulletin 44:203).

In 2007, the American College of Obstetricians and Gynecologists (ACOG) recommended that all women be offered aneuploidy screening before 20 weeks of gestation and that all women should have the option of invasive testing regardless of maternal age.

There are various screen tests available and choosing the most appropriate screening test can be confusing. Summarized below are the clinically relevant details of each test.

First Trimester Maternal Screen Test (MSFIRST)

- The first trimester screen test is optimally performed at 11 to 13 weeks of gestation.
- It involves sonographic determination of nuchal translucency (NT) and gestational age (by crown-rump length) combined with the serum markers pregnancy-associated plasma protein-A (PAPP-A) and human chorionic gonadotropin (HCG).
- This test does not screen for ONTD's, so second trimester screening for these defects still needs to be performed (Recommend MSAFP test).
- The results of DS and T18 screen are available in the first trimester. There is a higher risk for a positive result when the fetus does not have either disorder (false positive) compared to the Sequential or Integrated screen tests.
- This is the best screening test for women whose priority is privacy and early diagnosis; however, chorionic villus sampling (CVS), the diagnostic follow-up test, is associated with a higher risk of procedure related loss per woman screened than second trimester amniocentesis.

Sequential Screen Tests (MSSEQ1 and MSSEQ2)

- The Sequential Screen tests involve TWO blood draws, one in the first trimester and another in the second trimester as well as an ultrasound in the first trimester to measure the fetus' NT.
- The first trimester blood sample is tested for PAPP-A and total HCG.
- The second trimester blood sample is tested for Alpha fetoprotein (AFP), Total HCG, UE3 (Unconjugated Estriol) and Inhibin- A.
- The first trimester post test risk estimates will be provided ONLY if there is a high risk for DS or T18 (Greater than 1 in 25 cut off).
- If the first trimester test does not identify the pregnancy as being at increased risk, the post test risk estimates will be provided following the second blood draw in the second trimester. The second blood draw test results will be combined with the first trimester blood draw results to provide a final post test risk estimates.
- This testing has excellent detection capabilities for DS, T18 and ONTD's and a low chance of false positive test result.

Integrated Screen Tests (MSSINT1 and MSSINT2)

- The Integrated screening tests, like sequential tests as above involve TWO blood draws, one in the first trimester and another in the second trimester, with or without the inclusion of an NT measurement in the first trimester.
- The difference between the Sequential screen and the integrated screen is that the sequential screen provides first trimester results to women with a high risk for DS or T18.
- Since this test can be run with or without ultrasound measurement of NT, it provides an option to patients in areas where expertise in measurement of NT is not available.
- A disadvantage of the integrated test is that the patient has to wait until the second trimester to obtain her risk estimate.

A **positive screening test result** does not mean that a fetus definitely has a chromosome disorder, but only that an elevated risk has been detected. It is recommended that patients with a positive screen be referred for genetic counseling to discuss diagnostic and management options including fetal karyotype determination for definitive diagnosis. In the first trimester, karyotype is obtained by Chorionic villi sampling (CVS). In the second trimester, amniocentesis is performed to obtain amniocytes for chromosomal analysis. Analysis of the full karyotype is generally performed to allow detection of any aneuploidy (not just trisomy 21), as well as detection of major structural chromosomal abnormalities (eg, translocations, inversions, marker chromosomes). Patients who screen positive for ONTD's may be offered amniocentesis to measure the level of amniotic fluid AFP.

A **negative screening test result** means the patient's risk of having a baby with DS, T18 or ONTD is less than the specific cut-off level; it does not exclude the possibility of any of these defects, or that of another chromosomal disorder or congenital anomaly.

The below table shows the cut off and sensitivity and initial positive rates for the detection of Down syndrome.

Screen Test	DS Cut off	T18 Cut off	% Detection for DS	% False Positive for DS
MSFIRST	1 in 230	1 in 100	85	5-6
MSSEQ1	1 in 25	1 in 25	63	0.6
MSSEQ2	1 in 110	1 in 100	86 (Total)	1.6 (Total)
MSSINT1	NA	NA	NA	NA
MSSINT2	1 in 110	1 in 100	85 (Serum only) 87 (With NT)	3-4 (Serum only) 1.0 (With NT)



Effective, September 8, 2010, the following different maternal serum screen tests will be performed in house. There are no changes in specimen collection requirements, one full Gold/SST tube (Serum only). Specimen must be accompanied by a completed maternal screen test requisition. These tests will be performed daily, Monday thru Friday, with a turn around time of two to four days.

Mnemonic	Test Name
MSFIRST:	Maternal Screen, First Trimester ONLY
MSSEQ1:	Maternal Screen, Sequential #1
MSSEQ2:	Maternal Screen, Sequential #2
MSSINT1:	Maternal Screen, Integrated #1
MSSINT2:	Maternal Screen, Integrated #2

MSFIRST Maternal Screen, First Trimester ONLY

- First Trimester (Between 11 weeks 0 days and 13 weeks 6 days).
- Includes PAPP-A and Total HCG.
- Requires NT (Performed by a certified ultrasonographer)
- CRL measurements must be between 4.2-7.9 cm.
- This test does not screen for ONTD (Open Neural tube defects).
- MSAFP test is recommended in 2nd trimester to screen for ONTD.

MSSEQ1: Maternal Screen, Sequential #1

- First Trimester (Between 11 weeks 0 days and 13 weeks 6 days).
- Includes PAPP-A and Total HCG.
- Requires NT (Performed by a certified ultrasonographer)
- CRL measurements must be between 4.2-7.9 cm.
- Patient test results will be released only without risk estimates, unless pregnancy is at high risk (Greater than 1 in 25) for DS and T18 in the first trimester.
- Patients who are at medium to low risk after the first draw should go for the second draw (MSSEQ2) to complete the screen.

MSSEQ2: Maternal Screen, Sequential #2

- Requires previously submitted first trimester (MSSEQ1) specimen.
- Second Trimester (Between 15 weeks 0 days and 22 weeks 6 days) Best time is 16-18 weeks of pregnancy.
- Includes AFP, Total HCG, UE3 and Inhibin- A.

MSSINT1: Maternal Screen, Integrated #1

- First Trimester (Between 10 weeks 3 days and 13 weeks 6 days).
- Includes PAPP-A
- An Ultrasound for NT is optional for this test (if performed, must be done by a certified ultrasonographer).
- CRL measurements must be between 3.6-7.9 cm.
- Patient test results (PAPP-A) and Best time to draw the second specimen will only be reported without any risk estimates.
- Second specimen (MSSINT2) must be drawn to complete the screen.

MSSINT2: Maternal Screen, Integrated #2

- Requires previously submitted first trimester (MSSINT1) specimen.
- Second Trimester (Between 15 weeks 0 days and 22 weeks 6 days).
- Includes AFP, Total HCG, UE3 and Inhibin- A.
- Final interpretative report is available only when the second specimen results are complete.

Test Requirements:

The blood must be sent to the laboratory along with a **completed maternal screen test requisition**. The test requisition must be filled out completely as test interpretation is dependent upon this information; therefore results may be delayed if information is not provided or missing. Maternal demographic information such as age, weight, gestational age, diabetic state and race is used together with the results of the serum screen tests in a mathematical model to derive a risk estimate for each condition to identify women at increased risk of having an affected child. Results will be reported as “Normal” or “Abnormal” along with “Pre-Test” and “Post-Test” risk for each condition.

For any questions regarding methodology and interpretations, please contact:

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- **Genetic counselors** are available for questions through client services 508-334-2863



Changes in Testing for IgG Subclasses

In normal adults, immunoglobulin G (IgG) constitutes approximately 75 % of total serum immunoglobulins. IgG can be subdivided into four subclasses that are named in order of their abundance in the serum. IgG1 is the most abundant subclass, making up 60–70 % of total IgG followed by IgG2 (20–30 %), IgG3 (5–8 %), and IgG4 (1–4 %). The actual concentration of these subclasses may vary markedly among individuals.

Abnormal levels of one or more IgG subclasses have been documented in certain conditions including anaphylaxis, autoimmune diseases, and recurrent infections. More recently, high circulating levels of serum IgG4 have been proposed as a marker of autoimmune pancreatitis.

IgG subclass deficiency is a common finding in patients who have increased susceptibility to infections. IgG1 deficiency usually occurs in patients with severe immunoglobulin deficiency involving other IgG subclasses. IgG2 deficiency is more common in children and one of the most frequently identified disorders in patients with recurrent infections. Isolated deficiencies of IgG3 and IgG4 occur rarely and their clinical significance is not clear.

Despite their documented association with certain diseases, subnormal levels of one or more IgG subclasses are found in up to 20 % of normal population, and most individuals lacking these subclasses are asymptomatic. Consequently, levels of IgG

subclasses should be interpreted with caution and in conjunction with other laboratory and clinical findings.

Effective August 30th, 2010, testing for IgG subclasses will be performed at UMass Memorial Laboratories. This test may be indicated in patients with hypogammaglobulinemia or those with clinical evidence of possible immunodeficiency with normal or near-normal levels of total serum IgG. The test will continue to be performed on serum samples and will be run three times a week. There will be no changes in test mnemonic (GSUB) or sample requirements.

While total IgG level can be derived from the sum of levels of all subclasses (IgG1, IgG2, IgG3, and IgG4), a confirmatory and more precise test for total serum IgG is available and can be ordered separately (test mnemonic QIG).

The following table lists the new reference intervals for IgG subclasses.

If you have questions, comments or suggestions, please contact:

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IgG subclass	Reference Interval	
IgG1	0-2 years: 194–842 mg/dL	10-12 years: 423–1060 mg/dL
	2-4 years: 315–945 mg/dL	12-14 years: 342–1150 mg/dL
	4-6 years: 306–945 mg/dL	14-18 years: 315–855 mg/dL
	6-8 years: 288–918 mg/dL	18 years and older: 382–929 mg/dL
	8-10 years: 432–1020 mg/dL	
IgG2	0-2 years: 23–300 mg/dL	10-12 years: 76–355mg/dL
	2-4 years: 36–225 mg/dL	12-14 years: 100–455 mg/dL
	4-6 years: 61–345 mg/dL	14-18 years: 64–495 mg/dL
	6-8 years: 44–375 mg/dL	18 years and older: 242–700 mg/dL
	8-10 years: 72–430 mg/dL	
IgG3	0-2 years: 19–85 mg/dL	10-12 years: 17–173 mg/dL
	2-4 years: 17–68 mg/dL	12-14 years: 28–125 mg/dL
	4-6 years: 10–122 mg/dL	14-18 years: 23–110 mg/dL
	6-8 years: 16–85 mg/dL	18 years and older: 22–176 mg/dL
	8-10 years: 13–85 mg/dL	
IgG4	0-2 years: 1–78 mg/dL	10-12 years: 2–115mg/dL
	2-4 years: 1–54 mg/dL	12-14 years: 4–136 mg/dL
	4-6 years: 2–113 mg/dL	14-18 years: 11–157 mg/dL
	6-8 years: 0–99 mg/dL	18 years and older: 4–86 mg/dL
	8-10 years: 2–93 mg/dL	



Cytochrome P450 2D6 Mutation Analysis

Effective August 14, 2010, the UMass Memorial Molecular Diagnostic Laboratory will be offering mutation analysis of the cytochrome P450 2D6 isozyme. This isozyme is responsible, at least in part, for the bio-activation or inactivation (detoxification) of up to 25% of drugs in clinical use (1).

Many drugs are metabolized to inactive metabolites by CYP2D6. Examples of drugs that use CYP2D6 as a detoxification pathway are: amphetamines, selected beta-blockers, dextromethorphan, fluoxetine, lidocaine, mirtazapine, nefazodone, paroxetine, risperidone, ritonavir, thioridazine, tricyclic antidepressants, and venlafaxine. In addition, some drugs are bio-activated (prodrugs) by CYP2D6. Examples of prodrugs that use CYP2D6 as an activation pathway are: Tamoxifen, codeine and other opioids, hydrocodone, oxycodone, tramadol and encainide.

This Cyp2D6 assay identifies 17 alleles, including gene deletion and gene duplication, that lead to one of four metabolizer phenotypes: normal (extensive), intermediate, slow (poor) or ultra-rapid.

- Individuals with a **normal (extensive) metabolizer phenotype** are likely to have the expected response to standard doses of medications metabolized by CYP2D6. Genotypes consistent with the normal metabolizer phenotype include two functional CYP2D6 alleles or one functional and one reduced function CYP2D6 allele. Increased caution may be appropriate for individuals having one reduced function allele.
- Individuals with an **intermediate metabolizer phenotype** may require lower than standard dose of drugs metabolized to inactive metabolites by CYP2D6 but increased dose or an alternative treatment should be considered for prodrugs, like tamoxifen, that require activation by CYP2D6. Genotypes consistent with the intermediate metabolizer phenotype are those with one functional and one nonfunctional CYP2D6 allele, one functional and one reduced function CYP2D6 allele, or two reduced function CYP2D6 alleles.



- Individuals with **slow (poor) metabolizer phenotype** are at increased risk of drug-induced side effects due to diminished drug elimination, or for prodrugs, like tamoxifen, lack of therapeutic effect resulting from failure to generate the active form of the drug. In these cases, alternative treatment should be considered. Genotypes consistent with the poor metabolizer phenotype are those with two non-functional CYP2D6 alleles.
- Individuals with **ultra-rapid metabolizer phenotype** exhibit higher than average rates of drug metabolism by CYP2D6 enzyme and are at increased risk of therapeutic failure. Drugs which are deactivated by the CYP2D6 enzyme may require an increased dose. Drugs which are activated by CYP2D6 may require lower than average dosing. Genotypes consistent with ultra metabolizer phenotype include three or more active CYP2D6 alleles due to duplication of an active allele.

The test specimen requirement is one Lavender EDTA sample (room temperature) and results will be reported within 7 days. The following table lists the reference intervals for the cytochrome P450 2D6 isozyme.

Phenotype	Alleles Present	CYP2D6 Enzyme Activity
Poor (slow) metabolizer	Two non-functional	None
Intermediate metabolizer	One non-functional and one reduced-function One non-functional and one functional Two reduced-function	Very low Intermediate Intermediate
Normal (extensive) metabolizer	One functional and one reduced-function Two functional	Normal Normal
Ultra-rapid metabolizer	Three or more functional	High



Personalized drug therapy based on this information may improve drug efficacy and quality of life, as well as decrease the incidence of adverse drug effects.

Drug dose is also influenced by many non-genetic factors, including age, body weight, hepatic and renal function, concomitant diseases, nutrition, smoking, and drug-drug interactions.

CYP2D6 Inhibitors:

Co-administration of multiple drugs that inhibit CYP2D6 can decrease the rate of drug metabolism through the metabolic pathway. Some CYP2D6 inhibitors are: fluoxetine, quinidine, paroxetine, and celecoxib (3). For example, the co-administration of fluoxetine and/or paroxetine can convert a CYP2D6 extensive metabolizer to a phenotypic poor metabolizer.

CYP2D6 Inducers- No inducers of the CYP2D6 pathway have been found (3).

Alleles tested:

This assay tests for 16 alleles (*1, *2, *3, *4, *5 (gene deletion), *6, *7 *8, *9, *10, *11, *12, *14, *15, *17, and *41), and gene duplication of the CYP2D6 gene. The CYP2D6 *1 allele contains none of the tested mutations and is predicted to have normal activity. Allele *2 is associated with three different variants (-1584C>G; 166G>C; 2850C>T; and 4180G>C), but is associated with normal activity.

The following alleles are non-functional and are associated with a lack of enzymatic activity: *3 (2549delA), *4 (1846G>A), *5 (gene deletion), *6 (1707delT), *7 (2935A>C), *8 (1758G>T), *11 (883G>C), *12(124G>A), *14 (1758G>A) and *15 (138insT).

The following alleles are associated with reduced enzymatic function: *9 (2613-2615delAGA), *10 (100C>T), *17 (1023C>T), and *41 (2988G>A).

Allele	Mutation	Activity
*1	none	Normal
*2	-1584C>G in promoter; 1661G>C; 2850C>T; 1 4180G>C	Normal
*3	2549delA	Null
*4	1846G>A	Null
*5	gene deletion	Null
*6	1707delT	Null
*7	2935A>C	Null
*8	1758G>T	Null
*9	2613-2615delAGA	Reduced
*10	100C>T	Reduced
*11	883G>C	Null
*12	124G>A	Null
*14	1758G>A	Null
*15	138insT	Null
*17	1023C>T	Reduced
*41	2988G>A	Reduced
	gene duplication	Increased

Note: Other less frequent mutations not detected by this assay may be present in some patients.

In Caucasians, the most common null variant CYP2D6*4 is present in 15–21% of individuals. CYP2D6*10 allele associated with reduced enzyme activity is present in up to 57% of Asians and CYP2D6*17 in 20–34% of Africans and African Americans. The ultra-rapid phenotype is relatively rare in Caucasians and Asians, but commonly observed in Ethiopians (up to 30%).

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Changes in Measles, Mumps, Rubella and Varicella IgG Serology Testing



Measles Serology Screen:

Measles is a highly contagious, acute, exanthematous disease caused by the measles (rubeola) virus. It is generally self-limiting and without serious consequences, although complications such as bronchopneumonia and otitis media do occur. The most serious consequence, encephalomyelitis, is fortunately rare (about 1 in 10,000 cases). Natural infection with measles virus confers permanent immunity. Measles infection poses a serious threat to immunosuppressed, or immunocompromised patients. For these reasons, the laboratory diagnosis of measles has become increasingly important, notwithstanding the reduction in the incidence due to the introduction of vaccines.

The usual means of laboratory diagnosis of acute measles is serologic, either by the demonstration of a four-fold or greater rise in virus-specific IgG antibody in acute and convalescent serum pairs, or by the detection of virus-specific IgM antibody in a single, early, serum specimen.

It is very useful in the diagnosis of acute-phase infection with rubeola (measles) virus and in identifying non-immune individuals.

Mumps Serology Screen:

Mumps is a generalized illness characterized by fever and by inflammation and swelling of the salivary glands, particularly the parotid glands. Mumps is usually not severe in children, but in the adult the inflammation may involve the ovaries or testes (orchitis). Inflammation and swelling of the parotid glands (parotitis) in mumps infection is usually sufficiently diagnostic to preclude serological confirmation. However, inasmuch as one third of mumps infections are subclinical, viral isolation and/or some other serological procedure may be required.

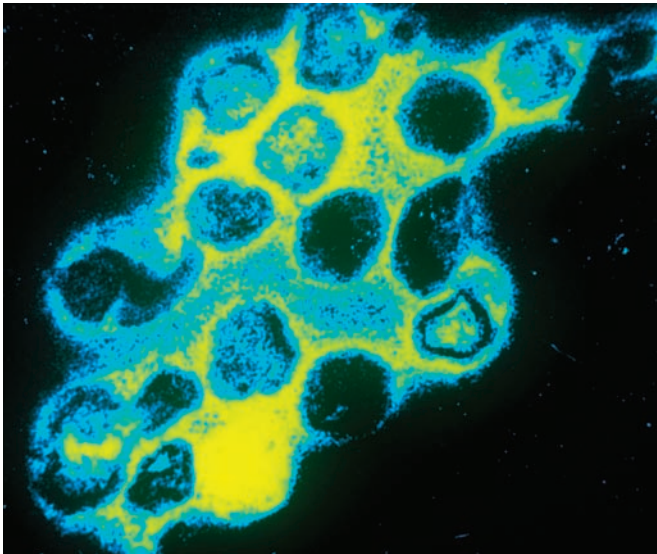
Virus isolation is cumbersome and time-consuming and is usually an impractical procedure for the typical clinical laboratory. Serodiagnosis of mumps infection has been accomplished by: neutralization, hemagglutination-inhibition (HI), indirect immunofluorescence and complement fixation (CF). These methods lack specificity, which limits their usefulness in determining immune status. The HI test also requires pretreatment of test sera to remove nonspecific inhibitors of hemagglutination.

Enzyme immunoassays (EIA, ELISA) are sensitive and specific and their sensitivity equals that of the neutralization test, and is greater than CF or HI. They are therefore, reliable tests for the determination of immune status. Serum IgM antibody testing should be obtained no earlier than three days following initial onset of symptoms. The test typically remains positive for up to four weeks but may be negative in up to 50 to 60 percent of specimens from individuals with acute disease who were previously immunized. A negative IgM titer in vaccinated individuals, therefore, does not rule out mumps. Immunity to mumps is established by demonstrating IgG antibodies on ELISA.

It is very useful in the diagnosis of acute-phase infection with mumps virus and in identifying non-immune individuals.



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Rubella Serology Screen

Rubella virus causes German measles, a mild sub clinical infection with a characteristic exanthem, affects both children and adults. Rubella is transmitted directly by contact or by droplets from the nasopharynx of infected individuals can cause significant birth defects if disease occurs early in fetal life. It has an incubation period of 14-21 days. Rubella is no longer endemic in the United States as a result of an intensive vaccination campaign. Minor epidemics occurred in the United States every five to seven years and major epidemics every 10 to 30 years. Individuals may shed virus for up to two weeks prior to the outbreak of rash; thus patients are typically infectious for some time before the infection becomes clinically obvious. Virus shedding decreases significantly after the appearance of the rash, a period coinciding with the development of neutralizing antibodies.

In general, 90% of the U.S. population has either been vaccinated or exposed to rubella. The presence of IgG antibodies in a single specimen is not sufficient to distinguish between active infection and past infection. The results of the test must be taken within the context of the patient's clinical history, symptomology and other laboratory findings. Patients suspected of having primary, active infection should be tested for the presence of IgM antibodies to rubella virus.

It is very useful in the determination of rubella immune status, in the diagnosis of rubella infection and to determine susceptibility to rubella, particularly in pregnant women.

Varicella Zoster Serology Screen:

Varicella Virus (VZV) infection causes two clinically distinct forms of disease. Primary infection with VZV results in Varicella (chickenpox), characterized by vesicular lesions in different stages of development on the face, trunk, and extremities. Herpes zoster, also known as "shingles", results from reactivation of endogenous latent VZV infection within the sensory ganglia. This clinical form of the disease is characterized by a painful, unilateral vesicular eruption, which usually occurs in a restricted dermatomal distribution. The diagnosis of these two diseases is usually made clinically. However, the use of diagnostic assays may be important in specific situations.

Test for VZV IgG antibodies is of use when clinical symptoms are present or infection suspected. Screening of the general population leads to no appreciable diagnostic advantage. Results from immunosuppressed patients should be interpreted with caution. It is very useful in the diagnosis of acute-phase infection with varicella virus and in identifying non-immune individuals. ELISA assays are suitable for screening for VZV susceptibility among healthcare workers. The rationale for this is that the risk of vaccinating an adult with a false-negative test result is much lower than the risk of natural infection in an individual falsely identified as seropositive. Routine screening for varicella in individuals born in the United States before 1980, who are not healthcare workers, is not recommended because of extremely high rates of seropositivity in this population.

- A positive IgG result coupled with a positive IgM result indicates recent infection with VZV. A positive IgG result coupled with a negative IgM result indicates previous exposure to VZV and immunity.
- A negative IgG result coupled with a negative IgM result indicates the absence of prior exposure to VZV and no immunity. However, a negative result does not rule out a VZV infection. Negative results in suspected early VZV infections should be followed by testing a new serum specimen in 2 to 3 weeks.

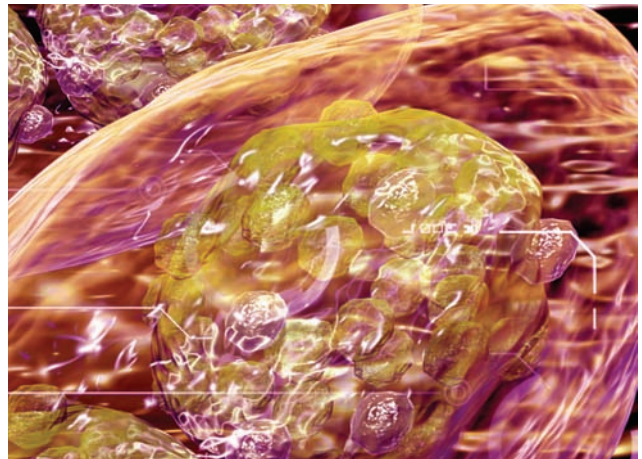




Image Courtesy of Department of Health and Human Services
Public Health Image Library (PHIL)

Effective August 30th, 2010, IgG serology testing for Measles (MEAL), Mumps (MUMS), Rubella (RUBS) and Varicella (VARY) will be performed using an automated multiplex immunoassay testing. The test will be performed on serum samples and will be available Monday through Friday. There will be no changes in the test mnemonics or sample requirements.

The test reports include a semi-quantitative value along with the test interpretation. The results of each antibody are expressed as an antibody index (AI). The numeric value of the test result is not indicative of the amount of the anti-Measles, Mumps, Rubella or VZV antibody present.

- For Measles, Mumps and VZV, results of ≤ 0.8 AI are reported as negative, results of 0.9 and 1.0 AI are reported as Equivocal, and results of ≥ 1.1 are reported as positive.
- For Rubella assay, results of ≤ 0.7 AI are reported as negative, results of 0.8 and 0.9 AI are reported as Equivocal, and results of ≥ 1.0 are reported as positive.

If you have questions, comments or suggestions, please contact:

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Interpretation of Results for Measles, Mumps and VZV

Result	Status	Interpretation
≤ 0.8 AI	Negative	No IgG antibodies specific to Measles, Mumps, or VZV detected. Patient is presumed to not have had a previous exposure to Measles, Mumps, or VZV through infection or vaccination.
0.9, 1.0 AI	Equivocal	Equivocal results: obtain an additional sample for re-testing.
≥ 1.1 AI	Positive	IgG antibody to Measles, Mumps, or VZV detected. This may indicate that the patient was exposed to Measles, Mumps, or VZV through infection or vaccination.

Interpretation of Results for Rubella IgG

Result	Status	Interpretation
≤ 0.7 AI	Negative	No Rubella specific IgG antibodies detected. Patient is presumed not to have had a previous exposure to Rubella through infection or vaccination.
0.8, 0.9 AI	Equivocal	Equivocal results: obtain an additional sample for re-testing.
≥ 1.0 AI	Positive	IgG antibody to Rubella detected. IgG antibody levels are at a level considered to indicate positive immunity.

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- To be a leading provider of laboratory services throughout New England, meeting the needs of patients and providers in the region, and
- To be one of the top ten academic medical center-based laboratories in the United States



East Cranston PSC 934 Park Avenue Cranston, Rhode Island

East Cranston PSC is located at 934 Park Avenue, Cranston, RI. The hours are Monday through Thursday 9:00am-6:00pm, Friday 9:00am-4:00pm, Saturday 9:00am-6:00pm, closed 12:00-1:00pm. The phone number at East Cranston PSC is 401-780-6746.