

EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT

Patient Name: Mrs. VIMALA

Patient DOB: 31/01/1996

EVIC Screen" is an evidence based prenatal screening program curated by Lilac Insights in accordance with the Fetal Medicine Foundation (UK)

guidelines for First Trimester Screening to determine the probality of most common chromosomal aneuploidies in a pregnancy. It utilizes:

- Hormonal values from the pregnancy measured on Fetal Medicine foundation (UK) accredited analyzers and reagents
- Robust indigenous medians from over 7 lac+ pregnancies for different gestation ages
- Risk calculations from evidence based algorithms validated through large international studies

UKNEQAS: United Kingdom National External Quality Assessment Service

RIQAS: Randox International Quality Assessment Scheme



The Risk Assessment Performed Using **CE-Marked Antenatal Risk Evaluation Software Certified by the British Standards Institute** (BSI)- ISO 13485:2016

RI	SK ASSESSMENT				MULTIPLE MEDIAN (I	
T21 (Down syndrome)	1:625	🥚 Intermediate Risk	LOW	INTERMEDIATE HIGH		
T18 (Edwards' syndrome)	1: 100000	Low Risk	LOW	HIGH	Free ß-hCG AFP	0.87
T13 (Patau syndrome)	1: 100000	Low Risk	LOW	HIGH	PAPP-A	0.88
Pre-eclampsia before 34 wee	ks 1:77	High Risk	LOW	HIGH	PLGF	0.27

INTERPRETATION

The First Trimester Enhanced Screening for the given sample is found INTERMEDIATE RISK for Downs Syndrome and Screen Positive PE.

SUGGESTIONS AND OTHER FINDINGS

• In view of intermediate risk (Risk between 1:251 to 1:1000), further counselling is recommended.

• Latest guidelines suggest further evaluation of intermediate risk patients by the following options as indicated:

a. Detailed anomaly scan and Genetic Sonogram to assess for markers and defects for chromosomal abnormalities.

b. Non-Invasive Prenatal Testing/Screening (NIPT) (Detection rate: >99%), ref: ISPD guidelines 2015.

c. Definitive testing through Fetal Karyotyping.

In view of PLGF MoMs observed in the mother, a focused maternal surveillance for development of High Blood Pressure and related problems and serial fetal growth and well being scans to monitor for onset of FGR can be considered.



Lab Reg. No. 90968

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Verified by Mr. Pradip Kadam Incharge Biochemistry (FMF ID: 147760)

Verified by Dr. Suresh Bhanushali MD (Path), Consultant Pathologist

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Patient name : Mrs. VIMALA

Sample ID: 2410003787

Sample Type:Serum

Risk assessment: Algorithm validated by SURUSS 2003, N.J Wald

Meenou. This res	olved Fluroimmunoass	dy					
			PREGNANC	Y DETAILS			
No. of fetuses GA is Based on	: 1 : CRL 72.2mm at 02 Parity : Null		EDD LMP Date Height	:05/09/2024 :29/11/2023 :157.5 cm	Age at Tern LMP Certa Weight	inty :Regu	lar
Smoking : None Parity : Nulliparous Height : 157.5 cm Weight : 58.16 Kg Ethinicity:Asian FHR :							
Sample ID Collection Date Scan Date GA at Coll Date GA at Scan Date Received on	: 2410003787 : 05/03/2024 : 02/03/2024 : 13 Weeks 5 Days : 13 Weeks 2 Days : 05/03/2024	CRL : CRL2 : BPD : BPD2 : HC : HC2 :	72.2 mm	Test Name Free-ß-hCG NB AFP NT PAPP-A PLGF MAP UTPI	Conc. 24.60 Present 09.59 1.8 5530.00 24.00 83.33 1.50	Unit ng/mL U/mL mm mU/L pg/mL mmHg	Corr. Mom 0.87 0.53 1.17 0.88 0.27 1.00 0.94

			RISKS		
Disorder: Do	own Syndrome			Result:	Intermediate Risk 👝
Final risk:	1:625	Age risk:	1:1110		
Cutoff	1:250	Risk type	Risk At Term		
Disorder: Ec	lwards' Syndrome			Result:	Low Risk
Final risk:	1:100000	Age risk:	1:9990		
Cutoff	1:100	Risk type	Risk At Term		
Disorder: Pa	atau Syndrome			Result:	Low Risk 👝
Final risk:	1:100000	Age risk:	1:29999		-
Cutoff	1:100	Risk type	Risk At Term		
Disorder: Pl	E < 34 weeks			Result:	High Risk
Final risk:	1:77				
Cutoff	1:100	Risk type	Risk at Term		





Verified by Dr. Suresh Bhanushali MD (Path), Consultant Pathologist Page 2 of 3







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PRENATAL SCREENING BACKGROUND

Every pregnant woman carries a certain degree of risk that her fetus/baby may have certain chromosomal defect/ abnormalities. Diagnosis of these fetal chromosomal abnormalities requires confirmatory testing through analysis of amniocytes or Chorionic Villous Samples (CVS). However, amniocentesis and CVS procedures carry some degree of risk for miscarriage or other pregnancy complications (Tabor and Alfirevic, 2010). Therefore in routine practice, prenatal screening tests are offered to a pregnant woman to provide her a personalised risk for the most common chromosomal abnormalities (T21-Down syndrome, T18- Edwards' syndrome, T13- Patau syndrome) using her peripheral blood sample. Based on this risk assessment, if the risk is high or intermediate, you can take informed decision of opting for invasive procedure such as amniocentesis or CVS followed by confirmatory diagnostic test(s), as per discussion with your clinician.

PRENATAL SCREENING TESTS ARE NOT CONFIRMATORY TESTS. THEY ARE LIKELIHOOD ASSESSMENT TESTS.

You may get your prenatal screening result as either of the following:-

High Risk

Low Risk

Intermediate

High Risk or Screen Positive Result: A High Risk Result does not mean that the pregnancy is affected with the condition. It means that the likelihood of the pregnancy having a condition is higher than the cut-off (Most commonly used cut-off is 1:250 and this represents the risk of pregnancy loss from confirmatory testing through CVS or amniocentesis).

Low Risk or Screen Negative Result: A Low Risk result does not mean that the pregnancy is not affected with a condition. It means that the likelihood of the pregnancy having a condition is lower than the cut-off.

Intermediate Risk result: An intermediate Risk result means that the pregnancy has an equivocal or a borderline risk of being affected with a condition. In this case, you may want to choose a second stage screening modality like a Non-invasive Prenatal Screening Test between 12 to 20 weeks of pregnancy before taking a decision on an invasive confirmatory testing. This will help you improve the sensitivity of the screening test keeping an invasive test a last option were you to come as a high risk in the second stage screening test.

SIGNIFICANCE OF MULTIPLE OF MEDIANS (MoMs)

Prenatal Screening determines the likelihood of the pregnancy being affected with certain conditions by analysing levels of certain hormones. These hormones are Feto placental products (released by Fetus or placenta). Their levels not only indicate propensity of the fetus being affected with certain chromosomal conditions, they also provide indication of placental insufficiency that can potentially lead to pregnancy complications like Pre-Eclampsia or Intra-Uterine Growth Restriction. It is therefore important to take cognisance of the Reported MoMs alongside the Risk results.

For more information, visit our website at: <u>www.lilacinsights.com/faq-pns</u>

DISCLAIMERS

Limitations of the Test:

As prenatal screening tests are not confirmatory diagnostic tests, the possibility of false positive or false negative results can not be denied. The results issued for this test does not eliminate the possibility that this pregnancy may be associated with other chromosomal or sub- chromosomal abnormalities, birth defects and other complications.

Nuchal Translucency is the most prominent marker in screening for Trisomy 13, 18, 21 in the first trimester and should be measured in accordance with the Fetal Medicine Foundation (UK) guidelines. Nuchal Translucency or Crown Rump Length measurement, if not performed as per FMF (UK) imaging guidelines may lead to erroneous risk assessments and Lilac Insights bears no responsibility for errors arising due to sonography measurements not performed as per these criteria defined by international bodies such as FMF (UK), ISUOG.

It is assumed that the details provided along with the sample are correct. The manner in which this information is used to guide patient care is the responsibility of the healthcare provider, including advising for the need for genetic counselling or additional diagnostic testing like amniocentesis or Chorionic Villus Sampling. Any diagnostic test should be interpreted in the context of all available clinical findings. As with any medical test, there is always a chance of failure or error in sample analysis though extensive measures are taken to avoid these errors.

- Quality of the Down syndrome screening program (Biochemical values, MoMs and Risk assessments) is monitored by UKNEQAS on an ongoing basis.
- This interpretation assumes that patient and specimen details are accurate and correct.
- Lilac Insights does not bear responsibility for ultrasound measurements like CRL,NT,NB etc. We strongly recommend that ultrasound measurements are performed as per FMF (UK)/ISUOG practice guidelines.
- PE risk stratification is done using a cut-off of 1:100 as per ASPRE study.
- It must be clearly understood that the results represent risk and not diagnostic outcomes. Increased risk does not mean that the baby is affected and
 further tests must be performed before a firm diagnosis can be made. A Low Risk result does not exclude the possibility of Down's syndrome or other
 abnormalities, as the risk assessment does not detect all affected pregnancies.
- Each sample received at Lilac Insights' processing centre is handled with the utmost sensitivity and care. All samples received on Sundays and National holidays are stored as per specific guidelines for the respective specimens and processed on the next day.

END OF REPORT



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