





To: Navjeevan Clinical Laboratory-Latur Saraswati Colony Thodga Road Ahamdpur Maharashtra Latur - 413515 Contact: 9130360462	Sample ID Patient ID Received on Registered on	2400123571 1002433058 14/06/2024 12:58 14/06/2024 19:38
Report Of: Mrs. SHATABDI SHINDE	Reported on	-
Pt. Contact:	Referred by Sonography by	DR.ANJALI UGILE DR.MAHESH PALMATE

EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT

Patient Name: Mrs. SHATABDI SHINDE

Patient DOB: 20/03/1990

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

	RISK ASSESSMEI	NT		
T21 (Down syndrome)	1:537	Intermediate Risk	LOW	INTERMEDIATE HIGH
T18 (Edwards' syndrome)	1:42234	Low Risk	LOW	HIGH
T13 (Patau syndrome)	1: 17908	Low Risk	LOW	HIGH

INTERPRETATION

The First Trimester Screening for the given sample is found Intermediate Risk for Down Syndrome.

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) Integrated screening with detailed Genetic Sonogram (Detection rate: 92-95%), ref: Kypros Nicolaides et al,

Fetal Diagn Ther 2014:35:174-184.

b) Non-Invasive Prenatal Testing/Screening (NIPT) (Detection rate: ;99%), ref: ISPD guidelines 2015. c) Definitive testing through Fetal Karyotyping.



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

Break

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

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Sample Type:Serum





Patient name : Mrs. SHATABDI SHINDE

Sample ID : 2400123571

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

Method:Electrochemiluminescence										
PREGNANCY DETAILS										
No. of fetuse	s :1		EDD	: 12/12/2024	Age at Terr	n :34.7	Years			
GA is Based of	GA is Based on : CRL 77mm at 11/06/2024		LMP Date	:09/03/2024	LMP Certainty : Unknown		iown			
Smoking : None Parity :		Height	:	Weight : 74.00 Kg						
Ethinicity:As	sian FHR :									
Previous pregnancy history			Pre-eclampsia history		Other findings					
Down syndrome Edwards' syndrome		PE in previous pregnancy		Insulin dependent diabetes						
Patau syndrome NTD syndrome		Pat. mother had PE		Chronic hypertension						
EDD: Estimated Due Date GA: Gestation Age LMP: Last Menstrual Period FHR: Fetal Heart Rate NTD: Neural Tube Defect PE: Pre-eclampsia DOB: Date										
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			SPECIMEN I	DETAILS						
Sample ID	: 2400123571	CRL :	77 mm	Test Name	Conc.	Unit	Corr. Mom			
Collection D	ate : 11/06/2024	CRL2 :		Free-ß-hCG	28.16	ng/mL	1.21			
Scan Date	: 11/06/2024	BPD :		PAPP-A	2566.00	mIU/L	0.54			
GA at Coll Da	ate : 13 Weeks 5 Days	BPD2 :								
GA at Scan D	Date : 13 Weeks 5 Days	HC :								
Received on	: 14/06/2024	HC2 :								
GA: Gestation Age / CRL: Crown Rump Length / BPD: Bi-parietal Diameter / HC: Head Circumference / free-ß-hCG: free-Beta Human Chorionic Gonadotropin										
NT: Nuchal Translucency / PAPP-A: Pregnancy-associated Plasma Protein-A										
RISKS										
Disorder: Down Syndrome Result: Intermediate Risk										
Final risk:	1:537	Age risk:	1:453							
Cutoff	1:250	Risk type	Risk At Term							
Disorder: Edwards' Syndrome Result: Low Risk										
Final risk:	1:42234	Age risk:	1:4074							
Cutoff	1:100	Risk type	Risk At Term							
Disorder: Patau Syndrome Result: Low Risk										
Final risk:	1:17908	Age risk:	1:12225							



1:100

Cutoff



(FMF ID: 147760)

Risk At Term

Risk type



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Sample ID: 2400123571

Patient name : Mrs. SHATABDI SHINDE

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:-



Low Risk

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).

Intermediate

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 an Integrated Screening Test that is done between 16 to 20 weeks of pregnancy or 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.

Note:

- 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 performed as per FMF (UK)/ISUOG practice guidelines.
- The above risk has been calculated based on Biochemistry values alone.
- 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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