

To: **Dr.Sushil Pawar C/O Pawar General Hospital Maternity Home & Fertility Centre-Sinnar**
Pawar General Hospital Maternity Home & Fertility Centre
Mahalaxmi Road Sinnar
Maharashtra
Nashik - 422103
Contact:
Report Of: Mrs. MIRA SACHIN SANGALE
Pt. Contact: 1000000000



Sample ID 2300115600
Patient ID 1002381427
Received on 16/09/2023 18:44
Registered on 16/09/2023 18:49
Reported on -
Referred by **Dr SUSHIL PAWAR**
Sonography by **Dr. ABHIJIT K KAPOTE**

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EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT

Patient Name: Mrs. MIRA SACHIN SANGALE

Patient DOB: 26/05/1991

EVICScreen™ 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 probability 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 ASSESSMENT

T21 (Down syndrome)	1: 670	● Intermediate Risk	LOW INTERMEDIATE HIGH
T18 (Edwards' syndrome)	1: 100000	● Low Risk	LOW HIGH
T13 (Patau syndrome)	1: 22000	● Low Risk	LOW HIGH

MULTIPLE OF MEDIAN (MoM)

Free β-hCG	1.99	●
PAPP-A	1.01	●

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 Nicolaidet 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.



UK NEQAS
International Quality Expertise
Lab Reg. No. 90968

Verified by
Mr. Pradip Kadam
Incharge Biochemistry

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

Patient name : Mrs. MIRA SACHIN SANGALE

Sample ID : 2300115600

Sample Type: Serum

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

Method: Electrochemiluminescence

PREGNANCY DETAILS

No. of fetuses : 1 EDD : 23/03/2024 Age at Term : 32.8 Years
 GA is Based on : CRL 59mm at 12/09/2023 LMP Date : 26/05/1991 LMP Certainty : Regular
 Smoking : None Parity : Height : Weight : 50.25 Kg
 Ethnicity: Asian FHR :

Previous pregnancy history

Down syndrome Edwards' syndrome
 Patau syndrome NTD syndrome

Pre-eclampsia history

PE in previous pregnancy
 Pat. mother had PE

Other findings

Insulin dependent diabetes
 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 of Birth

SPECIMEN DETAILS

Sample ID : 2300115600	CRL : 59 mm	Test Name	Conc.	Unit	Corr. Mom
Collection Date : 13/09/2023	CRL2 :	Free-β-hCG	84.82	ng/mL	1.99
Scan Date : 12/09/2023	BPD :	PAPP-A	5556.00	mIU/L	1.01
GA at Coll Date : 12 Weeks 4 Days	BPD2 :				
GA at Scan Date : 12 Weeks 3 Days	HC :				
Received on : 16/09/2023	HC2 :				

GA: Gestation Age | CRL: Crown Rump Length | BPD: Bi-parietal Diameter | HC: Head Circumference | free-β-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: 1:670 Age risk: 1:660	
Cutoff 1:250 Risk type Risk At Term	
Disorder: Edwards' Syndrome	Result: Low Risk ●
Final risk: 1:100000 Age risk: 1:5700	
Cutoff 1:100 Risk type Risk At Term	
Disorder: Patau Syndrome	Result: Low Risk ●
Final risk: 1:22000 Age risk: 1:8400	
Cutoff 1:100 Risk type Risk At Term	

Patient name : Mrs. MIRA SACHIN SANGALE

Sample ID : 2300115600

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

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

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

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: www.lilacinsights.com/faq-pns

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 ultrasound measurements are 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