



To: Shivneri Hospital-Pune

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Gavhanevasti, Bhosari,

Maharashtra

Pune - 411039

Contact:

Report Of: Mrs. VARSHA RAHUL KALE

Pt. Contact: 9021105354



# Sample ID 2301010191 Patient ID 1002381620 Received on 16/09/2023 18:23 Registered on 17/09/2023 12:34 Reported on - Scan QR code Referred by Dr. YOGESH ASHOK GADEKAR Sonography by Dr. SANTOSH SHAHARE

Patient DOB: 17/12/1994

### **EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT**

### Patient Name: Mrs. VARSHA RAHUL KALE

**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 ASSESSMENT ULTIPLE OF** T21 (Down syndrome) 1:550 Intermediate Risk INTERMEDIATE HIGH LOW Free ß-hCG 1.81 T18 (Edwards' syndrome) 1:100000 Low Risk HIGH PAPP-A 0.64 T13 (Patau syndrome) 1:31000 Low Risk LOW HIGH Pre-eclampsia before 34 weeks 1: 1400 Low Risk LOW HIGH

### **INTERPRETATION**

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

## **SUGGESTIONS AND OTHER FINDINGS**

- $\bullet \ \ \text{In view of intermediate risk (Risk between 1:251 to 1:1000), further counselling is recommended.}$
- 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.



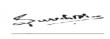




Verified by

Mr. Pradip Kadam

Incharge Biochemistry



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

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Patient name: Mrs. VARSHA RAHUL KALE Sample ID: 2301010191 Sample Type: Serum Risk assessment: Algorithm validated by SURUSS 2003, N.J Wald Method: Electrochemiluminescence PREGNANCY DETAILS No. of fetuses **EDD** :25/03/2024 Age at Term : 29.2 Years :1 GA is Based on : CRL 55mm at 12/09/2023 **LMP Date** : 12/06/2023 LMP Certainty : Regular Smoking: None Parity: 1 Prev. Preg Height : 158.0 cm Weight :48.90 Kg Ethinicity: Asian **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 of Birth SPECIMEN DETAILS Sample ID :2301010191 **CRL** :55 mm **Test Name** Conc. Unit Corr. Mom Free-ß-hCG 83.57 1.81 **Collection Date** : 13/09/2023 CRL2 ng/mL PAPP-A 3248.00 mIU/L 0.64 Scan Date : 12/09/2023 **BPD** BPD2: MAP 83.30 mmHg 1.00 **GA at Coll Date** : 12 Weeks 2 Days UTPI 0.95 0.60 **GA at Scan Date** HC : 12 Weeks 1 Days Received on : 16/09/2023 HC2 GA: Gestation Age | CRL: Crown Rump Length | BPD: Bi-parietal Diameter | HC: Head Circumference | free-B-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: 1:550 1:1100 Age risk: Cutoff 1:250 Risk type Risk At Term Disorder: Edwards' Syndrome Result: Low Risk Final risk: 1:100000 1:7800 Age risk: Cutoff 1:100 Risk At Term Risk type



Disorder: Patau Syndrome

Disorder: PE < 34 weeks

1:31000

1:100

1:1400

1:100

Final risk:

Final risk:

Cutoff

Cutoff



1:12000

Risk At Term

Risk at Term

Age risk:

Risk type

Risk type



Result:

Result:

Low Risk

Low Risk





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Patient name: Mrs. VARSHA RAHUL KALE Sample ID: 2301010191

### 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 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 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.
- 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**

