





Contact:     Regis       Report Of: Mrs. DURGA AMBALE     Regis       Pt. Contact: 9405799699     Refer       Image: Contact of the second secon
--

# EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT

## Patient Name: Mrs. DURGA AMBALE

Patient DOB: 12/04/2001

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					MULTIPLE OF MEDIAN (MoM)	
T21 (Down syndrome)	1: 144	High Risk	LOW	INTERMEDIATE HIGH	Free ß-hCG	13.5
T18 (Edwards' syndrome)	1:100000	Low Risk	LOW	HIGH	PAPP-A	0.88
T13 (Patau syndrome)	1: 100000	Low Risk	LOW	HIGH		
Pre-eclampsia before 34 wee	ks <b>1:111</b>	Low Risk	LOW	HIGH		

The First Trimester Screening for the given sample is found Screen Positive for Down syndrome.

# SUGGESTIONS AND OTHER FINDINGS

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

- Definitive testing through fetal karyotyping to confirm.
- In view of free bHCG MoMs observed in the mother, kindly consider correlation with fetal growth and well being scan at 28 30 weeks.



UK NEQAS

Break Verified by

Mr. Pradip Kadam

Incharge Biochemistry

Verified by **Dr. Suresh Bhanushali** MD (Path), Consultant Pathologist Page 1 of 3

Lilac Insights Pvt. Ltd. 301-302, Building A-1, Rupa Solitaire Millennium Business Park, MIDC Industrial Area, Sector-1, Navi Mumbai, Maharashtra 400710. Phone: +91 22 41841438; Website: www.lilacinsights.com; For queries or complaints, please email: info@lilacinsights.com | CIN - U85191MH2011PTC217513



Sample Type:Serum





Patient name : Mrs. DURGA AMBALE

Method:Electrochemiluminescence

Sample ID: 2300211465

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

PREGNANCY DETAILS												
No. of fetuse	s	:1		EDD	: 15/05/2024	Age at Tern	n :23.1	Years				
GA is Based o	on	: CRL 66mm at 07,	/11/2023	LMP Date	: 14/08/2023	LMP Certai	i <b>nty</b> :Regu	lar				
Smoking : None Parity : 1 Prev. Preg		Height	: 152.4 cm	Weight	Weight : 45.00 Kg							
Ethinicity:Asian FHR :												
Previous pregnancy history Pre-eclampsia history Other findings							dings					
Down syndrome Edwards' syndrome			PE in previous pregnancy		Insulin dependent diabetes							
Patau syndrome NTD syndrome			Pat. moth	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		:2300211465	CRL :	66 mm	Test Name	Conc.	Unit	Corr. Mom				
Collection Da	ate	:07/11/2023	CRL2 :		Free-ß-hCG	515.90	ng/mL	13.51				
Scan Date		:07/11/2023	BPD :		PAPP-A	4985.00	mIU/L	0.88				
GA at Coll Da	ate	: 12 Weeks 6 Days	BPD2 :		МАР	96.67	mmHg	1.20				
GA at Scan D	ate	: 12 Weeks 6 Days	HC :		UTPI	1.95		1.20				
Received on		:08/11/2023	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	5							
Disorder: Down Syndrome			Res	Result: High Risk								
Final risk:	1:144		Age risk:	1:1463								
Cutoff	1:250	)	Risk type	Risk At Term								
Disorder: Edwards' Syndrome Result: Low Risk												
Final risk:	1:100	0000	Age risk:	1:13159								
Cutoff	1:100	)	Risk type	Risk At Term								
Disorder: Patau Syndrome Result: Low Risk												
Final risk:	1:100	0000	Age risk:	1:39528								
Cutoff	1:100	)	Risk type	Risk At Term								
Disorder: PE < 34 weeks Result: Low Risk												
Final risk:	1:11	1										



Cutoff

UK NEQAS International Quality Experti Lab Reg. No. 90968

1:100

Broke Verified by **Mr. Pradip Kadam** Incharge Biochemistry

**Risk at Term** 

**Risk type** 



Page 2 of 3

Lilac Insights Pvt. Ltd. 301-302, Building A-1, Rupa Solitaire Millennium Business Park, MIDC Industrial Area, Sector-1, Navi Mumbai, Maharashtra 400710. Phone: +91 22 41841438; Website: www.lilacinsights.com; For queries or complaints, please email: info@lilacinsights.com | CIN - U85191MH2011PTC217513







Sample ID: 2300211465

### Patient name : Mrs. DURGA AMBALE

# 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

Intermediat Rick **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

Page 3 of 3



Lilac Insights Pvt. Ltd. 301-302, Building A-1, Rupa Solitaire Millennium Business Park, MIDC Industrial Area, Sector-1, Navi Mumbai, Maharashtra 400710. Phone: +91 22 41841438; Website: www.lilacinsights.com; For queries or complaints, please email: info@lilacinsights.com | CIN - U85191MH2011PTC217513