EVICTRIO IS Triple Integrated Screening

EVICScreen™ Evidence Based Comprehensive Screening

Lilac Insights™ passion • commitment • genetics

To: **Dandekar Clinic**
Agri Samaj Mandir Road, Old Panvel
Panvel Navi Mumbai - 410206
Maharashtra
Contact: 022-27452194
Report Of: APARNA AMIT PATIL
Pt. Contact: 8454060799

Sample ID	LI190024863
Patient ID	LI190246491
Received on	11-03-2019 18:48
Registered on	11-03-2019 18:48
Reported on	12-03-2019 15:49
Referred by	**Dr. Kanchan Divekar**
Sonography by	

EVICOSCREEN - EVIDENCE BASED COMPREHENSIVE PRENATAL SCREENING REPORT

Patient Name: _____ Patient DOB: _____

Ethnicity: _____ City: _____ Hospital ID: _____

Sample Type: Serum
Method: Time-resolved Fluroimmunoassay

Risk Assessment: Risk Assessment software accredited by Fetal Medicine Foundation (UK)

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 5 lac+ pregnancies for different gestation ages
- Risk calculations from evidence based algorithms validated through large international studies
- External audit of the prenatal screening program by United Kingdom National External Quality Assessment Service (UKNEQAS) scheme and Randox International Quality Assessment Scheme (RIQAS)

RISK ASSESSMENT

T21 (Down syndrome)	**1:**	Low Risk	LOW HIGH
T18 (Edwards' syndrome)	**1:**	Low Risk	LOW HIGH
Neural tube/ Abdominal wall defect	**1:**	Low Risk	LOW HIGH

MULTIPLE OF MEDIAN (MOM)

AFP	2.0
Free ß-hCG	1.0
uE3	2.0

INTERPRETATION

SUGGESTIONS AND OTHER FINDINGS

NABL ACCREDITED Certificate Number: MC-2731

UK NEQAS International Quality Expertise Lab Reg. No. 90968

Scientific Support: Bangalore Fetal Medicine Centre

Verified by
Mr. Pradip Kadam
Incharge Biochemistry

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

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PREGNANCY DETAILS

No. of Fetuses : 1 | **EDD** : 17-09-2019 | **Age at Term** : 27 Years
GA is Based on : CRL 64.9 mm on 11-03-2019 | **LMP Date** : 17-11-2018 | **LMP Certainty** : Irregular Cycle
Smoking: None | **Parity:** Nulliparous | **Height** : 160 cm | **Weight** : 50.70 kg
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

Assisted Reproduction: Donor Egg **Transfer Date:** 17-11-2018 **Extraction Date:** 17-11-2018 **Donor DOB:** 17-11-2018
Note! Age at term is calculated from the Donor DOB

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: : LI190024863 **CRL** : 64.9 mm
Collection Date : 11-03-2019 **CRL2** :
Scan Date : 11-03-2019 **BPD** :
GA at Coll Date : 12 Weeks 6 Days **BPD2** :
GA at Scan Date : 12 Weeks 6 Days **HC** :
Received on : 11-03-2019 **HC2** :

Test Name	Conc.	Unit	Corr. MoM
NT	1.2	mm	0.74
PAPP-A	8710.00	mU/L	1.85

SPECIMEN DETAILS

Sample ID: : LI190024864 **CRL** : 64.9 mm
Collection Date : 11-04-2019 **CRL2** : 64.9 mm
Scan Date : 11-04-2019 **BPD** : 64.9 mm
GA at Coll Date : 16 Weeks 6 Days **BPD2** : 64.9 mm
GA at Scan Date : 16 Weeks 6 Days **HC** : 164.90 mm
Received on : 11-04-2019 **HC2** : 164.90 mm

Test Name	Conc.	Unit	Corr. MoM
AFP	66.68	U/mL	1.74
free-ß-hCG	41.2	ng/mL	0.74
uE3	10.00	nmol/L	1.85

GA: Gestation Age | CRL: Crown Rump Length | BPD: Bi-parietal Diameter | HC: Head Circumference | NT: Nuchal Translucency
PAPP-A: Pregnancy-associated Plasma Protein-A | free-B-hCG: free-Beta Human Chorionic Gonadotropin | AFP: Alpha-Fetoprotein | uE3: Unconjugated Estriol

RISKS

Disorder: Down Syndrome **Result:** **Low Risk**
Final risk: 1:24365 Age risk: 1:1226
Cutoff: 1:250 Risk type: Risk At Term

Disorder: Edwards' Syndrome **Result:** **Low Risk**
Final risk: 1:100000 Age risk: 1:11028
Cutoff: 1:100 Risk type: Risk At Term

Disorder: Neural tube / Abdominal wall defect **Result:** **Low Risk**
Final risk: Age risk:
Cutoff: 1:100 Risk type: Risk At Term

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PRENATAL SCREENING BACKGROUND

- Every pregnant woman carry a certain degree of risk that her fetus/baby may have certain chromosomal defect/ abnormalities. Diagnosis of these fetal chromosomal abnormalities requires confirmatory testing by thorough analysis post amniocentesis or Chorionic Villous Sampling (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 personalized 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 AND THEY PROVIDE RISK ASSESSMENT RESULT AS

High Risk	**High risk or screen positive report-** which does not mean that the pregnancy is affected with these conditions. It means that you have a higher chance of having a baby with one of these conditions as compared to the chances of miscarriage that you have, if you opt for an invasive procedure.
Low Risk	**Low risk or screen negative report-** which does not mean that the pregnancy is not affected with these conditions. It means that you have a lower chance of having a baby with one of these conditions as compared to the chances of miscarriage that you have, if you opt for an invasive procedure.
Intermediate Risk	**Intermediate risk report-** which means that due to some parameters, the pregnancy can not be identified as a clear low risk or high risk for having either of the most common chromosomal aneuploidies. Further tests like Non-Invasive Prenatal Screening (InsighT/ InsighT-Adv/ InsighT Plus) or Integrated quadruple screening (done in second trimester) or invasive procedure (like amniocentesis or CVS) followed by definitive tests is recommended.

Based on a comparison of two risks (i.e. risk reported by screening test vs. risk of miscarriage associated with invasive procedure), the patient, guided by her clinician can decide on opting or rejecting definitive invasive testing.

SIGNIFICANCE OF MULTIPLE OF MEDIAN (MOM) VALUES OF HORMONES

Prenatal screening tests analyze the levels of fetoplacental hormones (hormones released by placenta or fetus) found in mother's blood sample. Their raised or grossly reduced levels not only provides indication for common chromosomal abnormalities like Down syndrome, Edwards' syndrome or Patau syndrome but also provide indication for placental insufficiency that can in some cases lead to late pregnancy complications such as Pre-eclampsia or Fetal Growth Restriction. This necessitates observation of the levels of hormones (MoMs) reported in the prenatal screening report besides looking at the reported risk estimates for holistic interpretation and clinical decision making.

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's Syndrome & ONTD screening program (Biochemical values, MoMs and Risk assessments) 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 the Ultra sound measurements.
- This is a risk estimation test and not a diagnostic test. An increased risk result does not mean that the fetus is affected and a low risk result does not mean that the fetus is unaffected. Reported risks should be correlated and adjusted according to the absence/presence of sonographic markers observed in the anomaly/malformation scan.
- The above risk has been calculated based on Biochemistry values alone.
- This interpretation assumes that patient and specimen details are accurate and correct. In all cases where an assessment of increased risk is based on LMP dates, the gestational age must be by ultrasound before further action is taken.
- 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.
- Lilac Insights does not bear responsibility for ultrasound measurements. The company strongly recommends that ultrasound scan is performed as per fetal Medicine Foundation (UK) Guidelines.

END OF REPORT

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Scientific Support
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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**