A new generation of prenatal screening software

PregSafe is a Windows®-based interpretive software tool for prenatal screening management. PregSafe calculates a pregnant woman's individual risk for carrying a fetus affected with Open Spina Bifida, Down Syndrome, Trisomy 18 and/or SLOS. This risk may be calculated in the First Trimester, based on maternal age, Nuchal Translucency and a wide choice of serum markers; and in the Second Trimester based on the classic Triple and Quad screen markers. Second Trimester risk of OSB may be confirmed using Amniotic Fluid AFP.

Intelligent Data Management

The Add/View Screen forms the cornerstone of the PregSafe system. The five segments contain patient demographic data, a list of pregnancies, requisitions, samples, and assay results.

Depending on the practices of your lab, there are several ways in which test results can be entered. For example, if patient and pregnancy data are entered before assays are performed, the assay results can be entered for all incomplete sample records through a separate screen.
Since the accuracy of gestational age determination is critical to the screening result, PregSafe automatically calculates the gestational age and suggests the best method of estimation after inputting existing data for LMP, CRL, BPD, Ultrasound, physical exam, and/or EDD.

Once you have established a sufficient number of samples in the database, you can calculate and use your own medians using a specified sample selection criteria. Medians used in PregSafe are corrected for weight, race, diabetes, and multiple gestations, and are then used to determine the MoMs for each sample. Adjustment factors for IVF and Smokers may also be used.

PregSafe generates a graphical interpretation of the risk calculation based on the cut-off values which you have specified.

Since knowing the pregnancy outcome is important in determining the effectiveness of your screening program, PregSafe generates outcome letters addressed to the referring physician requesting pregnancy outcome data which is then entered and viewed through another screen.
PregSafe allows you to define test panels so that you can accommodate a variety of screening models easily. Panel definition includes markers used, conditions tested and algorithms used for risk calculation. Available markers include:

- **First trimester**: Nuchal Translucency, PAPP-A, Free fl and Total hCG, Inhibin A
- **Second Trimester**: MSAFP, AFAFP, Free fl and Total hCG, uE3 and Inhibin A.

The OSB Prevalence and Cut-offs screen has data entry fields for the population prevalence of OSB, the cut-offs you want to use for serum (singleton and twin pregnancies) and amniotic fluid samples, and the prevalence factors for each race and diabetic populations. The system is shipped with default values.

You may assign different Downs and Trisomy 18 cut-offs for each test panel, so that you can adjust the Initial positive rates and detection rates for each panel independently.

PregSafe can store and apply a different set of medians and weight correction factors for each race or other sub-population group, for each biochemical marker. Alternatively you can use adjustment factors to calculate MoMs for one race based on the medians of another. In the case of NT measurements, a different set of medians can be stored for each sonographer, rather than for each race.
To speed up the data entry process, many of the entry fields in PregSafe can be assigned default values.

The Edit Message feature of PregSafe displays the full compliment of interpretive messages which require no initializing by the new user. You can customize these messages to reflect the needs of your lab.

PregSafe is designed with security in mind. Users are assigned user names, passwords and access rights, from browser access only to full access to patient data, system/clinical configuration, and altering medians and cut-offs. Users must login with their own password. An audit trail of all interpretations generated is maintained.

PregSafe is easily interfaced to either laboratory analyzers or information systems to assist you to automate your data entry and reduce the potential for entry errors.
Meeting your Reporting Needs

PregSafe will print interpretive reports based on your selection from five text and graphic formats. Your lab's name is hard-coded into the header of the report. These reports can be generated in batches, or individually.

A full range of administrative reports can also be printed. For example, you can verify the accuracy of your medians by generating a Median of MoMs report which checks your assay drift (from 1.00 MoM) month to month.

Distribution reports illustrate the characteristics of your screened population. The available distributions are Maternal Weight, Maternal Age, MoM, and Risk.
Second Trimester Prenatal Screening

PATIENT INFORMATION
NAME: Khan, Naseem
PATIENT CODE: NAKHAN
DOB: 02/14/74
LMP: 09/28/07
LOCATION:
PHYSICIAN:

CLINICAL INFORMATION
GESTATIONAL AGE: 16 weeks 3 days
from BPD of 35.0 mm on 02/13/08
MATERNAL AGE AT TERM: 34.4 years
MATERNAL WEIGHT: 68.5 kg
MATERNAL RACE: Asian
MATERNAL IDDM: No
GESTATION: Singleton
SCREENING STATUS: Initial sample

SPECIMEN
SPECIMEN CODE: NAKHAN
COLLECTION DATE: 02/13/08
RECEIVED: 02/13/08
REPORTED: 02/13/08

CLINICAL RESULTS

<table>
<thead>
<tr>
<th>Assay</th>
<th>Results</th>
<th>MoM</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFP</td>
<td>24.0 ug/L</td>
<td>0.66</td>
</tr>
<tr>
<td>uE3</td>
<td>0.79 ng/L</td>
<td>0.88</td>
</tr>
<tr>
<td>hCG</td>
<td>13.3 IU/mL</td>
<td>0.40</td>
</tr>
</tbody>
</table>

Risk Assessment (at term)
OSB: 1:41600
Down Syndrome: 1:3330
Age alone: 1:480
Equivalent Age Risk: < 15.0
Trisomy 18: 1:5670

Interpretation* (based on partial information supplied)

**DOWN SYNDROME** Screen Negative
The risk of Down syndrome is LESS than the screening cut-off. No follow-up is indicated regarding this result.

**OPEN SPINA BIFIDA** Screen Negative
The maternal serum AFP result is NOT elevated for a pregnancy of this gestational age. The risk of an open neural tube defect is less than the screening cut-off.

**TRISOMY 18** Screen Negative
These serum marker levels are not consistent with the pattern seen in Trisomy 18 pregnancies. Maternal serum screening will detect approximately 60% of Trisomy 18 pregnancies.

Accuracy of gestational age is essential for valid interpretation.

Printed 02/13/08 13:34:46
First Trimester Prenatal Screening

(not specified)

CLINICAL INFORMATION
GESTATIONAL AGE: 12 weeks 1 day from LMP of
MATERNAL AGE AT TERM: 25.5 years
MATERNAL WEIGHT: 55.0 kg
MATERNAL RACE: Caucasian
IDDM: No
GESTATION: Singleton
SCREENING STATUS: Initial sample

CLINICAL RESULTS

<table>
<thead>
<tr>
<th>Assay</th>
<th>Results</th>
<th>MoM</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAPP-A</td>
<td>1.00 IU/L</td>
<td>0.34</td>
</tr>
<tr>
<td>ß-hCG</td>
<td>44.0 IU/L</td>
<td>0.86</td>
</tr>
<tr>
<td>NT</td>
<td>1.0 mm</td>
<td>0.68</td>
</tr>
</tbody>
</table>

Risk Assessment (at term)

OSB: < 1:0
Down Syndrome 1:4750
  Age alone 1:1350
  Equivalent Age Risk < 15.0

Interpretation

DOWN SYNDROME

Screen Negative
The risk of Down syndrome is LESS than the screening cut-off.
The screen positive report shows the number and percent positive for each condition screened. Statistics are shown for both the initial and final screens, and for Down Syndrome, statistics are shown for mothers who are below and above the maternal age equivalent of the cut-off.

Other reports include: Interpretation Summary, List Test Status, Physician Usage, and Workload Summary.

Need PregSafe to do more?

We specialize in customizing software to meet your needs. We can modify various aspects of PregSafe (such as report format) or add additional components (such as tube labeling) to help create the ideal system for you.

We can also interface PregSafe to devices or LISs to greatly improve the speed, accuracy, and security of data entry. Contact us for more information.

PregSafe

Bringing prenatal screening management into the new millennium