

“When I began offering the test in 2004, physicians started by using the test on their high-risk patients – primarily women over 35 years of age. After a couple of months, when the physicians realized that the results are very accurate and it is a good screening method, they expanded testing to pregnant women of all ages.”

Clara Corona de Lau, CEO,
Biomedica de Referencia

In 2004, the award-winning reference laboratory Biomedica de Referencia in Mexico City pioneered the use of PRISCA Prenatal Risk Calculation software in Mexico. Working with Siemens, Clara Corona de Lau, CEO, has taken a leadership role in educating physicians about the benefits of noninvasive prenatal risk assessment, guiding them through the identification of patients who can benefit

most from this approach and supporting them with counsel as needed on the results. Today, the laboratory uses PRISCA software for first-trimester prenatal risk assessment on an average of about 30 patients a week. The benefits to patients and physicians are substantial, and early identification of potential problems can impact both outcome and cost of care.

Biomedica de Referencia Innovates Prenatal Risk Assessment

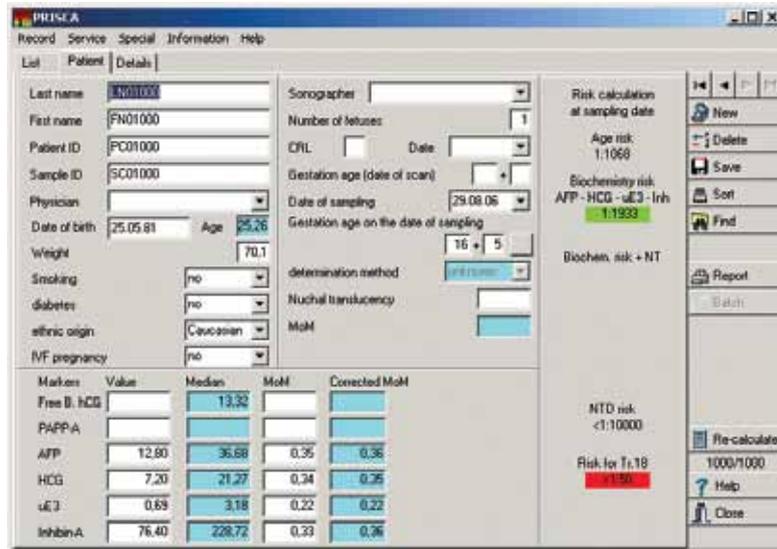
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PRISCA and IMMULITE: Enabling Noninvasive Prenatal Risk Assessment

At Biomedica de Referencia, prenatal risk assessment for first-trimester patients is based on the double-test protocol (PAPP-A and free β -HCG) on the IMMULITE® 1000 Immunoassay System, generally in combination with ultrasound measurements from nuchal translucency scans. PRISCA software, integrates IMMULITE and ultrasound data as well as the mother's age, the gestational age and other demographic data to calculate risk for Down syndrome (trisomy 21) and Edwards syndrome (trisomy 18). Patients are referred to Biomedica de Referencia by their obstetrician/gynecologists or sometimes the radiologists responsible for their ultrasound scans.



PRISCA user interface

“For me an important feature is that PRISCA includes internal medians. There’s no other program in the industry that has medians. This gives us a good starting point.”

Clara Corona de Lau, CEO,
Biomedica de Referencia

Once a patient is referred, she comes to Biomedica de Referencia for a blood draw, followed by PAPP-A and free β -HCG on the IMMULITE 1000 or 2000. The results are entered into PRISCA, along with patient information and ultrasound measurements. Within one or two days, the PRISCA report is ready for physician and patient review. The fast turnaround is consistent with the laboratory’s goal of providing good service to its physician clients.

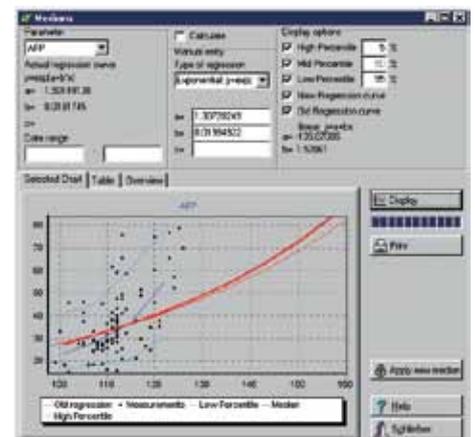
Benefits to patients and physicians

Ms. Corona de Lau attributes the increase in using PRISCA for prenatal risk assessment to the many benefits of early detection and the added safety of noninvasive testing. For the patient, early results (e.g., in the first trimester) allow the patient the option of early intervention or counseling if a problem is detected. And if no problem is identified, the patient can relax and enjoy the rest of her pregnancy. For the physician, PRISCA provides additional information to guide additional testing, prepare for potential problems and counsel patients about possible risks.

From the laboratory’s point of view, PRISCA is one more way to stay ahead of the competition by providing leading technology to improve care.

Selecting prenatal risk assessment software

According to Ms. Corona de Lau, PRISCA is unique in providing built-in medians. This saves time developing and validating medians. PRISCA also provides the flexibility to augment the database with results from her laboratory, adjusting the



PRISCA medians

“If the test shows that a baby has a condition such as an anencephalic brain and the pregnancy will abort spontaneously, the physician can counsel the patient and potentially reduce the emotional impact on the mother and drastically reduce the economic cost.”

“Conversely, when a patient knows that she has a low-risk pregnancy, she can feel more relaxed through the rest of her pregnancy.”

Clara Corona de Lau, CEO,
Biomedica de Referencia

medians as appropriate, and thus incorporate data more reflective of the patient population served. Working with Siemens, she plans to publish new data based on this work.

Even more important are quality measures to ensure accurate results. In the case of PRISCA, quality control measures are at two levels. At the data level, the accuracy of biomarker measurements is ensured with internal and external quality control procedures on the IMMULITE 1000. Correct input of ultrasound data is ensured with a built-in tool that compares ultrasound measurements by different providers, making sure they are in line with each other. At the statistical model level, PRISCA recognizes and reports unusual patterns – such as an atypical mix of normal vs. abnormal results for a particular physician. The laboratory also participates in peer group comparisons as another way to identify trends and/or data anomalies with PRISCA's SHARED DATABASE program.

Physician education is key

Today, Clara Corona de Lau, CEO of the laboratory, is a frequent presenter at medical symposia and conferences to spread the word about noninvasive prenatal risk assessment. She also publishes information on the laboratory's website about the interpretation of results. In addition, the laboratory's reports are customized to specific needs and reporting requirements for each physician. In 2010, she plans to convene a conference to follow up on progress made with PRISCA in the past few years.



Clara Corona de Lau, CEO,
Biomedica de Referencia

Founded in 1992 by Clara Corona de Lau, CEO, to set a new standard in clinical diagnostics in Mexico, Biomedica de Referencia is a leading reference laboratory serving Mexico City and surrounding areas. Since its founding, Biomedica de Referencia has experienced rapid growth due to its focus on innovation, quality and customer service, and it is the recipient of numerous awards including the National Quality Award. It has also been voted one of the top employers in Mexico and one of the 100 best places to work in Latin America. Currently, Biomedica de Referencia employs 92 people and continues to expand its capacity with the acquisition of additional analyzers and building of a new facility. For more information, please visit www.biomedicadereferencia.com.

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