



PRESS RELEASE
2019-02-12

Increased demand in the US for Miris Human Milk Analyzer

As milk analyzer company Miris received clearance by US Food and Drug Administration (FDA) to market its Miris Human Milk Analyzer™ (HMA) in December, doctors in the US for the first time have access to a test to help analyze the nutrients in breast milk. Miris HMA™ has been available since 2006 and the instrument is registered as a Medical Device in Europe, and Japan and is now also available in the US.

The interest for optimizing nutrition for preterm babies is growing in USA and the FDA approval has already proven to give effect as several Neonatal Intensive Care Units in the US have contacted Miris with interest in obtaining information and price quotes for the Miris HMA™.

"It is incredibly gratifying to see such a significant increase in quotation requests since the FDA approval of Miris HMA™ was announced in December last year", says Camilla Myhre Sandberg, CEO Miris. "It is the first instrument that has been approved as a diagnostic medical device for analyzing breast milk nutrients in the US. At present we have sent out over 50 quotes to prospective customers on neonatal units in the US. However, even though there are no real orders this is an indicator of great interest. Comparatively we sold a total of 60 Miris HMA™ during 2018".

Miris helps Neonatal Intensive Care Units and research institutes

The Miris Human Milk Analyzer™ uses an infrared spectroscopy system to analyze samples of human milk and provide a quantitative measurement of fat, protein and total carbohydrate content as well as calculations of the total solids and energy content contained in the milk. Data reviewed by FDA showed that the Miris Human Milk Analyzer test was effective at determining levels of protein, fat and carbohydrate in the milk. This is a prescription device intended for use by trained health care personnel at clinical laboratories.

"For the first time, doctors have access to a test to help analyze the nutrients in breast milk," said Courtney Lias, Ph.D. Director at the Division of Chemistry and Toxicology Devices in the FDA's Center for Devices and Radiological Health.

"While this test is not for everyone, it has the potential to aid parents and healthcare providers, mainly in a hospital setting, in better assessing the nutrient needs of certain babies who are not growing as expected," concludes Courtney Lias.

For more information:

Camilla Myhre Sandberg, VD Miris Holding AB
Cell phone: +46 18-14 69 07
E-mail: camilla.sandberg@mirissolutions.com

About Miris

Miris is a global company who develops, manufactures, markets and sells solutions for human milk analysis. The products are used at neonatal intensive care units, milk banks and research centers worldwide. The purpose is to enable clinicians to practice individualized nutrition of breast milk using target fortification, thus giving preterm babies the best possible start in life. Our mission is to make individualized nutrition, based on breast milk, available globally to improve neonatal health. Miris Holding AB is listed on the Spotlight Stock Market in Sweden.

This information is the information that Miris Holding AB is required to disclose under the EU Market Abuse Regulation. The information was provided by the above contact person for publication on February 12, 2019.