News From the Food and Drug Administration

Eye-Tracking Test Approved to Help Diagnose Concussion

A noninvasive test that doesn't require comparison with a baseline assessment before an injury occurred has received FDA approval to help diagnose concussion in children and adults.

Marketed as EyeBox, the test is approved for use in pediatric patients aged 5 years or older and in adults 67 years or younger. It tracks a person's eye movements while he or she watches a 4-minute video clip that moves clockwise around a computer monitor. Research has correlated certain eye movements with a higher likelihood of concussion. Abnormalities in eye movements also have been linked with elevated intracranial pressure.

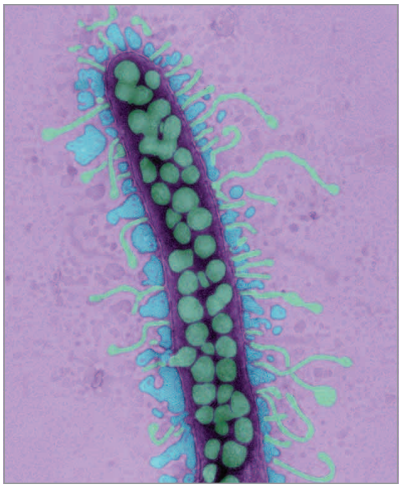
The FDA's approval was based on a study involving 282 patients at 6 independent US clinical sites. Investigators compared the patients' Eyebox results with a clinical reference standard for concussion in patients presenting to emergency departments and sports medicine clinics with a suspected head injury. EyeBox was both sensitive in identifying patients with concussion and specific in ruling out concussion.

"Development of treatments for concussion is challenging because there are few reliable outcome measures," John Leddy, MD, medical director of the University at Buffalo Concussion Management Clinic, said in a statement from EyeBox's New York City–based manufacturer, Oculogica Inc. The recently approved test "may offer one solution to this challenge, providing researchers with an objective oculomotor assessment," Leddy added.

FDA Approves Bacteriophage Trial

The first US clinical trial of intravenously administered bacteriophage therapy has received FDA approval. Physician researchers at the University of California San Diego (UCSD) School of Medicine will conduct the trial in collaboration with AmpliPhi Biosciences Corporation, a San Diego–based biotechnology company.

Bacteriophages are viruses that feed on bacteria. Their clinical use as infectious disease fighters dates back to the early 1900s, but they fell out of favor a few decades later when antibiotics arrived. Now, with multidrug-resistant infections on the rise, bacteriophages are garnering new attention.



The proposed phase 1 and 2 trial will evaluate the safety, tolerability, and efficacy of an experimental bacteriophage therapy for patients with ventricular assist devices (VAD) who have developed *Staphylococcus aureus* infections. The therapy will include antibiotic treatment. About 10 patients will be enrolled in the trial.

"There is a high, unmet need in patients with *S aureus* VAD infections, which are typically very difficult to eradicate with conventional antibiotic therapy," principal investigator Saima Aslam, MD, medical director of the Solid Organ Transplant Infectious Disease Service at UC San Diego Health, said in a statement.

Bacteriophage therapy and UCSD made headlines in recent years after a psychiatry professor there, Tom Patterson, PhD, received the treatment for a life-threatening, multidrug-resistant *Acinetobacter baumannii* infection. The FDA granted emergency approval for Patterson's treatment. Since then, several other patients also were approved for the therapy.

Largely positive results prompted UCSD to join forces last year with other research institutions and biotechnology companies to launch the Center for Innovative Phage Applications and Therapeutics (IPATH), the first of its kind in North America. The recently approved trial will be the first for IPATH, which was created within the UCSD medical school with a primary goal to conduct rigorous clinical trials of phage therapies.

Measuring Breast Milk Nutrients to Support Optimal Infant Growth

A recently approved diagnostic test will help health care professionals measure the nutrient content of breast milk to guide care for infants that may be at risk of growth failure.

The Miris Human Milk Analyzer uses an infrared spectroscopy system to analyze human milk samples and quantitatively measure fat, protein, and total carbohydrate content as well as calculate the milk's total solids and energy content. The analyzer is a prescription device intended for use by trained health care personnel at clinical laboratories.

Analyzing breast milk "has the potential to aid parents and health care providers, mainly in a hospital setting, in better assessing the nutrient needs of certain babies who are not growing as expected," Courtney Lias, PhD, director of the FDA's Division of Chemistry and Toxicology Devices, said in a statement.

Because breast milk composition varies among women, it sometimes doesn't contain sufficient protein and energy levels for infants with increased nutrient needs. Knowing the macronutrient content can help the health care team and parents make informed decisions on how to fortify breast milk to meet an infant's individual needs.

The FDA's approval was based on analyses of the same 112 human milk samples in the Miris device and by an independent method. Each analysis provided similar results. Although the Miris analyzer effectively determined protein, fat, and carbohydrate levels, the FDA noted that certain circumstances—medications a nursing mother may be taking, for example—could interfere with the device's accuracy.

The agency also said health professionals should use the analysis results in conjunction with clinical assessments such as weight and growth in creating an infant's nutritional management plan. **– Rebecca Voelker, MSJ**

Note: Source references are available online through hyperlinks embedded in the article.

Thomas Deerinck/National Center for Microscopy and Imaging Research/UC San Diego