LumiraDx™ Case Study

Use of the LumiraDx SARS-CoV-2 Antigen Test in pediatric practice

Introduction

Dr Andre B Gvozden has been in practice for over 40 years, is a board certified pediatrician, fellow of the American Academy of Pediatrics and Clinical Assistant Professor of Pediatrics at University of Maryland. Dr Gvozden runs `Gvozden Pediatrics' which is a group practice that specializes and provides care for child and adolescent health based in Millersville, MD, USA.

"The LumiraDx Platform is rapid and easy to use – in the times of COVID-19 we need something like this,that is accurate, intuitive with minimal steps."

The practice

The busy practice has 4 partners and serves around 3000 patients, 85% of those patients being children and a busy adult practice that has grown as child patients have grown into adults and stayed with the practice because of the strong and trusting relationships that have been established over many years.

The LumiraDx Platform

During Spring 2020 Dr Gvozden was introduced to the SARS-CoV-2 Antigen Test on the LumiraDx Platform as part of a clinical study. Over the last 10 years, Dr Gvozden has spent time evaluating lots of different point of care instruments/platforms for respiratory pathogens, urine and serum testing. In that time, LumiraDx has been the only one of those that he has assessed that has made him say "I must have this device".

During the use of the platform at his practice, Dr Gvozden reported that he "experienced zero glitches, which has not been the case with previously assessed point of care tests. With other tests, it can be frustrating to spend $20-30 on a test only to end up with an invalid result or error".

How did the Platform fit into your practice?

"The use of the LumiraDx Platform fits well into the flow of the practice. The short waiting time means that staff do not have to spend much time away from the patient. It is easy to use, has a short waiting time (12 minutes), and the staff training needed to have the platform up and running is minimal."

What did your patients think?

"Patients liked the speed of the test and the fact that they could leave knowing their test results – which is a real benefit when it is not easy in the community to get tested. Patients are able to trust a result which comes from their Doctor, and they see it as being `Doctor recommended'. This gives a sense of confidence."

Dr. Andre B. Gvozden, MD
Pediatrics Specialist in Millersville, MD, with over 40 years of experience in the medical field

"The accuracy figures are impressive, the test has been well designed and the technology works great."

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For use by healthcare professionals only. Products not available in all countries or regions. Available in the USA under FDA Emergency Use Authorization.
In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.