



## **FDA Stops Emergency Use Authorization Review of SQI Diagnostics RALI-Dx™ IL-6 Severity Triage Test for COVID-19 Patients**

*FDA cites de-prioritization due to high volume of EUA reviews; recommends other approval pathway for this test*

**TORONTO, July 23, 2021. SQI Diagnostics Inc. (the “Company” or “SQI”) (TSXV: SQD) (OTCQB: SQIDF)**, a precision medicine company that discovers, develops and commercializes innovative rapid diagnostic testing for healthcare professionals, patients and consumers worldwide, announces that FDA will not continue its review of SQI’s submission of the RALI-Dx™ IL-6 Severity Triage Test for Emergency Use Authorization under the “Tests for Management of COVID-19 Patients” category. The agency cites a high volume of EUA requests and its prioritization of EUA reviews according to factors including the public health need for the product and shortages of critical devices during the pandemic. The FDA has encouraged SQI to submit an application under a non-EUA regulatory pathway.

“This decision is disappointing for SQI,” stated Mr. Clive Beddoe, Interim CEO. “We were encouraged by the positive dialogue with the FDA throughout the review process, and we will continue with our efforts to seek FDA regulatory clearance for this product in the US. The RALI-Dx™IL-6 Severity Triage Test has broad applicability in helping to identify patients with severe inflammatory response arising from COVID-19 and other causes of respiratory distress. We are confident that the FDA prioritization will support our upcoming COVID-19 HOME Antibody Test submission under the EUA regulatory pathway.”

### **About SQI Diagnostics**

SQI Diagnostics is a life sciences and diagnostics company that is leading the way in healthcare utilizing state-of-the-art technology to rapidly diagnose, triage and provide medical insights to patients. We strive to improve people’s lives and assist their healthcare providers by providing quality clinical health information backed by years of research and clinical data. For more information, please visit [www.sqidiagnostics.com](http://www.sqidiagnostics.com).

#### **Contact:**

Chief Financial Officer  
Morlan Reddock  
416.674.9500 ext. 277  
[mreddock@sqidiagnostics.com](mailto:mreddock@sqidiagnostics.com)

## FORWARD-LOOKING INFORMATION

*This press release contains certain words and statements, which may constitute “forward-looking statements” within the meaning of applicable securities laws relating to future events or future performance and reflect the current expectations and assumptions of the Company regarding its growth, results of operations, performance, business prospects and opportunities. These statements generally can be identified by use of forward-looking words such as “may”, “would”, “could”, “will”, “should”, “expect”, “plan”, “estimate”, “anticipate”, “intends”, “believe”, “potential”, or “continue” or the negative thereof or similar variations. The Company’s actual results and performance discussed herein could differ materially from those expressed or implied by such statements. Such statements are qualified in their entirety by the inherent risks and uncertainties surrounding future expectations. Important factors that could cause actual results to differ materially from expectations include, among other things, general economic and market factors, competition, the effect of the global pandemic and consequent economic disruption, and the factors detailed in the Company’s ongoing filings with the securities regulatory authorities, available at [www.sedar.com](http://www.sedar.com). Although the forward-looking statements contained herein are based on what we consider to be reasonable assumptions based on information currently available to us, there can be no assurance that actual events, performance or results will be consistent with these forward looking statements, and our assumptions may prove to be incorrect. Readers are cautioned not to place undue reliance on these forward-looking statements. The Company undertakes no obligation to publicly update or revise any forward-looking statements either as a result of new information, future events or otherwise, except as required by applicable law.*

*Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*