Corewell Health

Corewell Health Laboratory

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Device Recall: Bordetella pertussis/parapertussis PCR

Effective Date: June 24, 2025

Laboratory Bulletin

On June 24, Corewell Health Laboratories was made aware of a device recall for the test system used to perform the Bordetella pertussis/parapertussis PCR test [LAB9520]. It was determined that there could be a false positive rate of up to 16.7% for *Bordetella parapertussis* when using the affected reagent lots. Results for *Bordetella pertussis* are not expected to be affected at this point.

Results as far back as 03/04/2024 may be affected. All results of "*Bordetella parapertussis* Detected" between 03/04/2024 and 06/25/2025 should be evaluated as potential false-positive results and correlated clinically. If indicated, additional confirmatory testing should be performed.

Until the device recall ends or alternative testing methods can be established locally, all specimens with "*Bordetella parapertussis* Detected" results will be sent for confirmatory testing, which will delay reporting but ensure accurate results.

If you have questions, please contact your Beaumont Laboratory Customer Service Department:

• Corewell Health Reference Lab Customer Service: 800-551-0488 or 248-551-1155, Option 5

Date submitted: June 26, 2025
Submitted by: Dr. Benjamin von Bredow, Technical Director, Microbiology