QuidelOrtho™

URGENT

June 17, 2025

URGENT FIELD SAFETY NOTICE
Potential for False Positive Results with QuickVue® Dipstick Strep A Test

Dear Valued Customer,

The purpose of this notification is to inform you of the potential for false positive results with QuickVue® Dipstick Strep A Test.

Affected Product Name	Product Code (Unique Device Identifier)	Affected Lot(s)	Expiry
QuickVue® Dipstick Strep A Test, 50T	**20108** (30014613201083)	709673 709676 709484 709501 709520 709535	05-FEB-2026 05-FEB-2026 09-JAN-2026 09-JAN-2026 16-JAN-2026 16-JAN-2026
QuickVue® Dipstick Strep A Test, 25T	**20125** (30014613201250)	709487 709503 709509 709684	09-JAN-2026 16-JAN-2026 16-JAN-2026 12-FEB-2026
QuickVue® Dipstick Strep A Test, 50T, SCN	**20108SC** (0130014613330073)	709485 709502	09-JAN-2026 16-JAN-2026

Summary
QuidelOrtho™ received complaints regarding false positive results from customers testing with the QuickVue® Dipstick Strep A Test. False positives may include faint pink lines as well as pink-to-red Test lines.

Impact to Results
QuidelOrtho confirmed there is an increase in false positive results, as low as 10% and as high as 40% for certain lots of QuickVue Dipstick Strep A.

Positively biased Strep A results may impact clinical judgement regarding or continued provision of antibiotic therapy in patients with suspected infection, potentially contributing to inappropriate antibiotic use.

The QuickVue Dipstick Strep A test is used in acute patient management; QuidelOrtho does not recommend a review of previous patient results as such review would not be able to detect impacted results without repeat testing of the patients who are unlikely to be ill at

the time of review. Such a review is unlikely to impact patients' management. The results from any diagnostic test should be evaluated in conjunction with a patient's history, risk factors, clinical presentations, signs, and symptoms, and other test results. Please consult your Medical Director regarding any additional actions.

As of 09-JUN-2025, QuidelOrtho has received 31 complaints relating to this issue with no reports of adverse effects.

REQUIRED ACTION

- Discontinue using, render unusable, and discard your remaining inventory of the above listed lots of QuickVue Dipstick Strep A Test.
- Review the content of this communication with your Medical Director and retain this letter for your laboratory.
- Complete and return the enclosed Confirmation of Receipt form no later than **June 25, 2025**. Upon receipt of your completed Confirmation of Receipt form, QuidelOrtho will replace your discarded inventory, as needed.
- Please forward this notification if the affected product was distributed outside of your facility.

Contact Information
We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact Global Services Organization at 1-800-874-1517 or technicalsupport@quidelortho.com.

Enclosures: Confirmation of Receipt form (Ref. CL2025-159a_EU_CofR)