



QuickVue® TLI

Technical Bulletin

QuickVue TLI H. pylori Stool Antigen Test Stability

The recommended storage for the QuickVue TLI H. pylori Stool Antigen Test is between 2°C to 8°C. Stress stability studies were conducted for the QuickVue TLI H. pylori Stool Antigen Test to assess performance if the test is not stored per the recommended conditions. Representative sample lots were tested after being stored at temperatures of $\leq -10^{\circ}\text{C}$, 2°C to 8°C, prevailing Room Temperature and $\geq 37^{\circ}\text{C}</math> for 72 hours. The kits were found to continue to meet acceptance criteria as listed in the Final QC SOP for the QuickVue TLI H. pylori Stool Antigen Test and gave equivalent results to a reference kit retained at the recommended storage temperature of 2°C to 8°C. The testing procedure challenges analytical sensitivity and specificity using standard curves of antigen, as well as External Controls. Performance testing was conducted in triplicate. The analysis demonstrated no effects to performance of the assay.$

These tests were performed to represent a worst-case scenario of shipping failure and do not represent expectations of our normal validated shipping methods which include transfer from our facility via refrigerated carrier and distribution using overnight shipping via a preferred carrier.

We do not recommend storing the kits outside of their stated storage conditions. However, in the event that kits were **not** stored between 2°C to 8°C and were accidentally frozen for less than 3 days (72 hours) or stored at temperatures up to 37°C for a maximum of 3 days (72 hours), the kit performance should be acceptable.

Further information: If the tests were stored incorrectly, performance should be assessed immediately with kit External Controls.

Caution: We cannot guarantee that the kits will meet their intended shelf life if they were not stored between 2°C to 8°C.

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com.

You may also visit our website at quidel.com for information on Quidel's line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Products (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, SDS, and Package Inserts.