

URICULT CLIA COMPLIANCE REFERENCE GUIDE

When reporting results as only a COLONY COUNT (Numeric value) ↓	When reporting results as GROWTH or NO GROWTH (positive or negative) ↓	When reporting the PRESUMPTIVE ID of colony growth ↓
MODERATELY COMPLEX	MODERATELY COMPLEX	HIGHLY COMPLEX
<p style="text-align: center;"><u>PT TESTING:</u></p> <p>No standard proficiency survey required but must participate in a biannual assessment program*.</p> <p style="text-align: center;"><u>QUALITY CONTROL:</u></p> <ul style="list-style-type: none"> • No QC testing required • Visually inspect Uricult vials for contamination, excess moisture, and damage before use. • Remove Certificate of Analysis from package insert <p style="text-align: center;"><u>DOCUMENTATION:</u></p> <p>Required to maintain a log book with the following information:</p> <ul style="list-style-type: none"> • Verification of visual inspection of Uricult paddles. • Lot # and exp. date • The daily monitoring of incubator temperature. • The Certificate of Analysis from the package insert. 	<p style="text-align: center;"><u>PT TESTING:</u></p> <p>Required to enroll in a standard proficiency survey program which includes 5 samples to be tested 3 times a year.</p> <p style="text-align: center;"><u>QUALITY CONTROL:</u></p> <ul style="list-style-type: none"> • Required to perform QC testing that includes a positive and negative control on each new lot number. • Visually inspect Uricult vials for contamination, excess moisture, and damage before use. • Remove Certificate of Analysis from package insert. <p style="text-align: center;"><u>DOCUMENTATION:</u></p> <p>Required to maintain a log book with the following information:</p> <ul style="list-style-type: none"> • Verification of visual inspection of Uricult paddles. • Lot # and exp. date • The daily monitoring of incubator temperature. • QC results • The Certificate of Analysis from the package insert. 	<p style="text-align: center;"><u>PT TESTING:</u></p> <p>Required to enroll in a standard proficiency survey program which includes 5 samples to be tested 3 times a year.</p> <p style="text-align: center;"><u>QUALITY CONTROL:</u></p> <ul style="list-style-type: none"> • Required to perform QC testing for 5 organisms** (representative to the organisms reported by your laboratory) for each new lot number. • Biochemical testing*** <u>recommended</u> to confirm presumptive ID of colonies. • Visually inspect Uricult vials for contamination, excess moisture, and damage before use. • Remove Certificate of Analysis from package insert. <p style="text-align: center;"><u>DOCUMENTATION:</u></p> <p>Required to maintain a log book with the following information:</p> <ul style="list-style-type: none"> • Verification of visual inspection of Uricult paddles. • Lot # and exp. date • QC test results • The daily monitoring of incubator temperature. • The Certificate of Analysis from the package insert.

* Available through API 800-333-0958 (catalog # 811) or check with your State Proficiency Service

** Suggested organisms: E. Coli, Staph Auerus, Proteus Vulgaris, Pseudomonas, Enterococcus.

*** Biological testing material can be purchased from your distributor.