



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 IDENTIFICATION of colony growth
MODERATELY COMPLEX	MODERATELY COMPLEX	HIGHLY COMPLEX
<p style="text-align: center;"><u>PROFICIENCY TESTING</u></p> <p>No standard proficiency survey required but must participate in a bi-annual assessment program*</p>	<p style="text-align: center;"><u>PROFICIENCY 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>PROFICIENCY 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> <p>1 a - Prepare IQCP Risk Assessment</p> <p style="text-align: center;">OR</p> <p>b - Perform a positive and Negative Control**** with each new shipment or Lot Number every 6 months</p> <p style="text-align: center;">AND</p> <p>2 Visually inspect Uricult vials for damage, contamination and excess moisture before use</p> <p>3 Remove Certificate of Analysis from package Insert and save</p>	<p style="text-align: center;"><u>QUALITY CONTROL</u></p> <p>1 a - Prepare IQCP Risk Assessment</p> <p style="text-align: center;">OR</p> <p>b - Perform a positive and Negative Control**** with each new shipment or Lot Number every 6 months</p> <p style="text-align: center;">AND</p> <p>2 Visually inspect Uricult vials for damage, contamination and excess moisture before use</p> <p>3 Remove Certificate of Analysis from package Insert and save</p>	<p style="text-align: center;"><u>QUALITY CONTROL</u></p> <p>1 Required to perform QC testing for 5 organisms (representative of the organisms tested by your laboratory) for each new LOT number**</p> <p>2 Biochemical testing recommended to confirm presumptive ID of colonies***</p> <p>3 Visually inspect Uricult vials for damage, contamination and excess moisture before use</p> <p>4 Remove Certificate of Analysis from package Insert and save</p>
<p style="text-align: center;"><u>DOCUMENTATION</u></p> <p>Required to maintain a log book with the following information:</p> <p>1 Verification of visual inspection of Uricult paddles</p> <p>2 LOT number and expiration date</p> <p>3 The Daily monitoring of incubator temperature</p> <p>4 The Certificate of Analysis from the Package Insert</p> <p>5 QC test results</p>	<p style="text-align: center;"><u>DOCUMENTATION</u></p> <p>Required to maintain a log book with the following information:</p> <p>1 Verification of visual inspection of Uricult paddles</p> <p>2 LOT number and expiration date</p> <p>3 The Daily monitoring of incubator temperature</p> <p>4 The Certificate of Analysis from the Package Insert</p> <p>5 QC test results</p>	<p style="text-align: center;"><u>DOCUMENTATION</u></p> <p>Required to maintain a log book with the following information:</p> <p>1 Verification of visual inspection of Uricult paddles</p> <p>2 LOT number and expiration date</p> <p>3 The Daily monitoring of incubator temperature</p> <p>4 The Certificate of Analysis from the Package Insert</p> <p>5 QC test results</p>

*Available through API; (1-800-333-0958 - 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 Gibson Bioscience 800-477-4763

****Uricult Control Set available from LifeSign 800-526-2125