



## Document Information:

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**Specification**

<b>Test</b>	<b>Test Procedure</b>	<b>Specification</b>
Visual Inspection	SOP 180.05.05	<p><b><u>Inspect 10 kits</u></b></p> <p>Each COBAS PCR URINE KIT contains a minimum of 100 COBAS PCR URINE PACKETS.</p> <p><b><u>Sample 50 packets from each of the 10 kits (500 total packets)</u></b></p> <p>Each COBAS PCR URINE PACKET contains one vial of COBAS PCR Media, 4.3 mL and one disposable transfer pipette (large bulb).</p> <p>Each packet is securely sealed. Product information, batch number and expiration date are printed on the back of the packet.</p> <p><b><u>Accept/Reject Criteria = 7/8</u></b></p> <p>If the total defects of the 500 sample packets are <math>\leq 7</math>, the lot is acceptable. If the total defects are <math>\geq 8</math>, the lot is unacceptable.</p>
Verification of Electronic Package Insert	SOP 180.05.05	<p>Verify the existence of Electronic Package Insert (ePI).</p> <p>Verify the existence of Electronic Instructions for Use (eIFU).</p>