

CLIA Compliance Manual for AcT diff2 Series Analyzer

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TAB 5: MSDS

4C[®] Plus Cell Control, Abnormal Low, Abnormal High and Normal
S-CAL[®] Calibrator
diff AcT PAK[™]
diff AcT Tainer[™]
AcT RINSE SHUTDOWN DILUENT

How to Use This Manual

Getting Started with the AcT diff 2 Series Analyzer

	Where to Find Help
Before You Begin Testing Patients	
Step 1: Sign up with the CLIA Program, if necessary, by filling out the CLIA application (CMS Form 116) and mailing or faxing it to your state CMS office.....	Tab 1
Step 2: Enroll in a Proficiency Testing program.....	Tab 3
Step 3: Install the AcT diff 2 Series Analyzer:	
– Perform method validation using the Method Validation Worksheet	Tab 4
– Use the Lab Personnel Training Checklist to train those who will test patient samples.....	Tab 2
Step 4: Read this manual and fill-in-the-blanks to indicate your exact procedures for testing:	
– Sign off on the procedures you customized using the Policies and Procedures Approval Form on the following page.....	Page ii
Once Testing Has Begun	
Each Day of Testing:	
– Run QC and ensure that QC results are within the correct range before testing patients.....	Tab 2
– Take humidity and temperature readings of the room where testing is performed. Also take a temperature reading of the refrigerator where reagents are stored. Record on the Temperature/Humidity Chart	Tab 2
Once a Month:	
– Complete the Monthly QA Checklist	Tab 2
Three Times Per Year:	
– Perform proficiency testing and mail results back to the PT Agency.....	Tab 1
Once Every Six Months:	
– Perform calibration and document on the Calibration Worksheet	Tab 3
Annually:	
– Evaluate testing personnel using the Lab Personnel Evaluation Checklist	Tab 1