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Roche Diagnostics has made every reasonable effort to ensure that all the information contained in this manual is correct at the time of printing However, Roche COBAS INTEGRA Systems Assay Information 400/400 plus 800 D-1-Antitrypsin AAT2 0-008 0-008 mg/dL 0 100

Attachment 5 JAN I 6 2009 510(k) Summary COBAS INTEGRA ...

510(k) Summary - COBAS INTEGRA 4001800 Bilirubin Total Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence Submitter Roche Diagnostics name, address, 9115 Hague Rd contact Indianapolis IN 46250 (317) 521-4569

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the Cobas 6000 and data entry in the StarLIMS host computer system may be done manually or these tasks may be executed via a barcode-based bi-directional interface The Cobas 6000 can utilize both of these two systems simultaneously

User s Guide - Medical Laboratory Equipment

COBAS MIRA System User's Guide 5 Daily Startup — Summary (For details see COBAS MIRA Maintenance and ISE Maintenance sections) Daily Operation 1 Switch on the COBAS MIRA analyzer 2 Enter "Operator Code" and "Password" if required 3 Perform daily maintenance (COBAS MIRA System and ISE) according to the maintenance log sheet

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Page 6 Host Interface manual cobas® 4800 system Host interface Manual DRAFT Overview 3 Workflow Communication Scenarios The following table shows the communication scenarios existing for the cobas 4800 Table 1 Communications Scenarios Name Description Input Output Work Order Inquiry Full The cobas 4800 ask the LIS to get order details for one

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