Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0536588	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Usphs Indian Hospital Laboratory	1700 Cerrillos Road, Santa Fe, NM	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A validation survey was conducted on 3/18/2026. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and manufacturer's instructions, the laboratory failed to ensure their written policies were consistent with one another for one of one test (Prothrombin Time/International Normalized Ratio). Findings included: 1. Review of the laboratory's procedure "SFIHC Laboratory General Policy and Procedure - Specimen Collection Lab-010" stated, "Prothrombin Time(PT) [sic], Stability: Centrifuge for no less than 15 min @ RT on an unopened tube. Test plasma immediately. Samples can be stored frozen and tested within 36 hrs. PT/Inr could be safely stored up to 24 hours refrigerated." 2. Review of the laboratory's CA-600 procedure for specimen handling stated, a) "Onsite collection: Centrifuge blood specimen in Stat Express 4 centrifuge for 10 minutes at 4500 rpm. If immediate testing is done, plasma may remain on packed cells or it can be separated from the packed red cells. Patient specimen(s) in unopened tubes that have not been centrifuged can be kept at 18-24C and tested within 24 hours from collection time." b) "Offsite collection: Patient specimen(s) in unopened tubes that have not been centrifuged should be kept at 18-24C and tested within 24 hours from collection time. Do not store specimen(s) at 2 to 4C, which may result in cold activation of Factor VII and therefore alter PT results. If testing is not completed within 24 hours, plasma (that has been separated from the packed cells) must be frozen at -20C. Frozen plasma can

	be stored for up to two weeks ..." 3. Review of the Innovin manufacturer's instructions stated, "Do not store at 2 to 8C as cold activation of FVII may alter results ...Please refer to CLSI document H21-A5 for detailed information on sample preparation." The laboratory's procedure "Lab-010" included refrigerating PT/INR specimens for 24 hours and the CA-600 procedure and manufacturer's instructions stated to not refrigerate.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's procedure manual, direct observation, and interviews, the laboratory failed to follow the manufacturer's instructions for three of three CA-600 reagents' onboard stability. Findings included: 1. Review of Siemens CA-600 series manufacturer's instructions (applications sheets revision 5.02) stated, "On-board stability Dade Innovin Time (h) 24 ...CA CLEAN I Time (h) 24". Review of a notification from Siemens for "CA-CLEAN II on-board-stability time on the CA-600 series" stated, "Sysmex Corp. internal investigations have shown that after transferring of the CA CLEAN II from the original bottle into a suitable cup, an on-board- stability of 7 hours can be guaranteed on the Sysmex CA-600 instrument series." 2. Review of the laboratory's CA-600 procedure for Innovin on-board stability stated, "24 hours." 3. During an observation of the CA-600 analyzer on 3/18/2026 at 11:07 am, Innovin, CA CLEAN I and CA CLEAN II were observed on-board and in-use. The bottle of Innovin (lot #564657D, expiration date 11/23 /2026) was labeled with an open date of 3/13/2026 and expiration date of 3/23/2026. 4. During an interview on 3/18/2026 at 3:30 pm, testing person-12 (TP-12) stated the reagent holder in the CA-600 analyzer is taken off the instrument (with the Innovin, CA-CLEAN I, and CLEAN II) every afternoon, stored in the refrigerator, then taken out the next day to place back on the analyzer for use. 5. During a telephone interview on 3/20/2026 at 8:51 am, the surveyor asked the Siemens technical support representative whether it was an acceptable practice for the laboratory to remove the reagent holder off the CA-600 (with the Innovin, CA-CLEAN I, and CLEAN II) every afternoon to store it in the refrigerator, then take out the next day to place back on the analyzer for use. The representative stated the laboratory must follow the on-board stability from the application sheets (24 hours) and the notification for the CA-CLEAN II (7 hours). The laboratory failed to follow manufacturer's instructions for reagent on-board stability on the CA-600 analyzer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's procedure manual, direct observation, and interviews, the laboratory failed to label three of three reagents with prepared and revised expiration dates that were on the CA-600 analyzer. Findings included: 1. Review of Siemens CA-600 series manufacturer's instructions (applications sheets revision 5.02) stated, "On-board stability Dade Innovin Time (h) 24 ...CA CLEAN I Time (h) 24". Review of a notification from Siemens for "CA-CLEAN II on-board-stability time on the CA-600 series" stated, "Sysmex Corp. internal investigations have shown that after transferring of the CA CLEAN II from the original bottle into a suitable cup, an on-board- stability of 7 hours can be guaranteed on the Sysmex CA-600 instrument series." 2. Review of the laboratory's CA-600 procedure for Innovin on-board stability stated, "24 hours." 3. During an observation of the CA-600 analyzer on 3/18/2026 at 11:07 am, Innovin, CA CLEAN I and CA CLEAN II were observed on-board and in-use. The bottle of Innovin (lot #564657D, expiration date 11/23/2026) was labeled with an open date of 3/13/2026 and expiration date of 3/23/2026. The laboratory did not label the Innovin with the 24-hour on-board stability and did not label CA CLEAN I and CA CLEAN II with on-board stability times of 24 hours and 7 hours, respectively. 4. During an interview on 3 /18/2026 at 3:30 pm, testing person-12 (TP-12) stated the reagent holder in the CA-600 analyzer is taken off the instrument (with the Innovin, CA-CLEAN I, and CLEAN II) every afternoon, stored in the refrigerator, then taken out the next day to place back on the analyzer for use. 5. During a telephone interview on 3/20/2026 at 8: 51 am, the surveyor asked the Siemens technical support representative whether it was an acceptable practice for the laboratory to remove the reagent holder off the CA-600 (with the Innovin, CA-CLEAN I, and CLEAN II) every afternoon to store it in the refrigerator, then take out the next day to place back on the analyzer for use. The representative stated the laboratory must follow the on-board stability from the application sheets (24 hours) and the notification for the CA-CLEAN II (7 hours).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and in interview with TP-12, the laboratory failed to ensure one of two CA CLEAN II bottles were not expired and available for use. Findings included: 1. During a tour of the laboratory on 3/18/2026 at 11:26 am, a bottle of CA CLEAN II in an open box was observed stored near the CA-600 analyzer. The bottle and box included lot #Q5006, "op 2/10/26", and manufacturer's expiration date of 3/12/2026. 2. Review of the CA CLEAN II manufacturer's instructions stated, " ...9. Do not use an outdated product." 3. During an interview on 3/18/2026 at 11:26 am, TP-12 confirmed the expired CA CLEAN II was in-use and on board the CA-600 analyzer.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)

	(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with laboratory staff, the laboratory failed to ensure statistical parameters used to establish their chemistry QC acceptable criteria were defined and available for five of five lot numbers. Findings included: 1. Review of the current Biorad QC ranges (Unity Peer Group records) for the Cobas analyzer included the following: Immunology Lot #85750 (expiration date 2/28/2026), Multiqual 1, 2, 3 Lot #56770 (expiration date 8/31/2027), Diabetes Lot #85880 (expiration date 9/30/2026), Urine Chemistry Lot #1007100 (expiration date 6/30/2027), and Cardiac Markers Plus LT Lot #1003100 (expiration date 10/31/2026). 2. During an interview on 3/18/2026 at 3:22 pm, the surveyor asked the laboratory staff for the statistical parameters used to establish QC acceptability criteria (for current lot numbers) for Cobas analyzer. The technical consultant stated the person who was responsible for that was no longer with the laboratory.