Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2324970	01/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Schaumburg Lab	1325 N Meacham Rd - Ste 100b, Schaumburg, IL	

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
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 laboratory policies and procedures, laboratory non-waived test volume worksheet, lack of documentation, and interview with general supervisors (GS #1 and GS #2) and the technical supervisor (TS); the laboratory failed to have procedures in place for 40 of 40 analytes listed on the laboratory non-waived test volume worksheet and performed on the Roche Cobas Pro SSU (Serial Number: 2504-03) from the start of patient testing, 11/18/2025 through to date of survey, 01/21/2026 affecting five patients reviewed in the subspecialty of routine chemistry. Findings include: 1. Upon tour of the laboratory on 01/20/2026, at 1:28 pm, surveyors observed a Roche Cobas Pro SSU analyzer (Serial Number: 2504-03) utilized for patient testing in the subspecialty of routine chemistry. 2. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have procedures in place for 40 of 40 analytes performed on the Roche Cobas Pro SSU analyzer: Alanine Aminotransferase (ALT/AGPT) Albumin Alkaline phosphatase (ALP) Amylase Alanine Aminotransferase (ALT/SGPT) Aspartate Aminotransferase (AST/SGOT) Bilirubin, Total (TBI) Bilirubin, Direct (DBI) Blood Urea Nitrogen (BUN) Calcium (Ca) Carcinoembryonic Antigen (CEA) Chloride (Cl) Cholesterol, Total (CHOL) Cholesterol, High Density Lipoprotein (HDL) Cholesterol, Low Density Lipoprotein (LDL) Carbon Dioxide Content (CO2) Creatinine, Blood (CREA) Creatine phosphokinase (CPK) Ferritin Gamma-Glutamyl Transferase (GGT) Glucose, Blood (GLU) Iron, Total Lactic Dehydrogenase (LDH) Magnesium Phosphorous Potassium (K) Protein Total (TP) Prostate Specific Antigen (PSA) Sodium (Na) Triglycerides

	(TGL) Troponin (TNT) Uric Acid C-Reactive Protein (CRP) B-type natriuretic peptide (Pro Bnp) Cancer Antigen (CA125) Cancer Antigen (CA15-3) Cancer Antigen (CA19-9) Human Chorionic Gonadotropin (hCG) Thyroid Stimulating Hormone (TSH) Thyroxine (Free T4) 3. Review of randomly selected patients reports revealed laboratory had resulted and reported five patients' tests from the Cobas Pro SSU while no standard operating procedure was in place. Test Date: Patient Id: Test: 12/16/2025 GE37940004 CMP/Lipid 12/16/2025 GE15353906 CMP/Lipid 12/16 /2025 GE15348966 CMP/ CRP/TSH/T4 01/06/2026 GE12662583 CMP/Lipid/TSH 01 /06/2026 GE15361999 Troponin * CMP = comprehensive metabolic panel ** CRP = C-Reactive protein *** TSH = Thyroid Stimulating Hormone ^* T4 = Thyroxine 4. Interviews with GS #1, GS #2 and the TS on the second date of survey, 01/21/2026, at 03:54 pm, confirmed the laboratory failed to have procedures in place for all tests performed per 493.1251 on the Roche Cobas Pro SSU (Serial Number: 2504-03) from the start of patient testing, 11/18/2025 through to date of survey, 01/21/2026.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, the Food and Drug Administration (FDA)'s laboratory test complexity database and interviews with the general supervisors (GS) and the technical supervisor (TS); the laboratory failed to perform verification studies for Erythrocyte Sedimentation Rate (ESR) testing in the specialty of Hematology on the Alcor iSED Elite from the start of testing 08/28/2025 to the date of survey, 01/21/2026, affecting 362 patients. Findings include: 1. Direct observation upon tour of laboratory on 01/20/2026, at 1:28 pm, surveyors observed the Alcor iSED Elite analyzer (Serial Number: 120006103) being utilized for patient testing. 2. Review of the FDA's laboratory test complexity database found that the use of "the Alcor iSED Elite analyzer" was not FDA approved. 3. Review of laboratory records found the laboratory failed to establish performance specifications for the Alcor iSED Elite analyzer before reporting patient test results for the following characteristics: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. 4. Review of the laboratory non-waived test volume worksheet indicated 362 patient tests were performed on the Alcor iSED Elite analyzer for Sediment Rate (ESR) from August 2025 through December 2025. 5. Interviews with GS #1, GS #2 and the TS on date of survey, 01/21/2026, at 03:54 pm, confirmed the laboratory

	failed to perform verification studies for Erythrocyte Sedimentation Rate (ESR) testing in the specialty of Hematology on the Alcor iSED Elite from the start of testing 08/28/2025 to the date of survey, 01/21/2026, affecting 362 patients.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: A. Based on direct observation during tour of laboratory, review of laboratory records, quality control (QC) records, lack of documentation, and interviews with the general supervisors (GS) and the technical supervisor (TS); the laboratory failed to ensure external quality control (QC) materials were run each day of testing and before reporting patient test results for three of three patients reviewed on the two BD Affirm VPIII analyzers as required per 493.1256 from the start of patient testing 08/28/2025 through to survey, 01/21/2026 affecting three patients reviewed. Findings include: 1. Upon direct observation on the first date of survey, 01/20/2026, at 1:28 pm, surveyors observed two BD Affirm VPIII analyzers, A (Serial number: A606016) and B (serial number: A605026) being utilized for patient testing. 2. Review of laboratory policies and procedures revealed policies titled, "MOL.12:BD Affirm VPIII Microbial Test" which states under "External Quality Control", "Tri-valent Positive and Negative Quality Controls are external quality control. These are run every 30 days, new lot and or/new shipment whichever comes first as stated in the IQCP." 3. Review of laboratory policies and procedures found no IQCP for BD Affirm VPIII testing using analyzer A and analyzer B (See D5445-B). 4. Review of QC records revealed a lack of documentation of external QC results for each day of testing on both BD Affirm VPIII analyzer A and analyzer B from the start of patient testing 08/28/2025 through date of survey, 01/21/2026. 5. Interview with the TS on 01/21/2026 at 10:15 am stated, the laboratory did not run external daily control materials because they thought the IQCP was completed and authorized by the LD. 6.Review of patient reports revealed three patients' results were reported when daily external control results were not recorded: Test Date: Patient Id: Test: 09/03/2025 GE11248345 Vaginitis Panel 10 /21/2025 GE36777662 Vaginitis Panel 11/12/2025 GE15126880 Vaginitis Panel 7. Additional interviews with GS #1, GS #2 and the TS on date of survey, 01/21/2026, at 03:54 pm, confirmed the laboratory failed to ensure external QC materials were run each day of testing and before reporting patient test results on two of two BD Affirm VPIII analyzers as required per 493.1256 affecting three patients reviewed. B. Based on direct observation during tour of laboratory, review of laboratory records, quality control (QC) records, lack of documentation, and interviews with the general supervisors (GS) and the technical supervisor (TS); the laboratory failed to ensure external quality control (QC) materials were run each day of testing and before reporting five of five patient test results on the Cepheid GeneXpert analyzer as required per 493.1256 from the start of patient testing 08/28/2025 through survey

	date, 01/21/2026 affecting five patients reviewed. Findings include: 1. Upon direct observation on the first date of survey, 01/20/2026, at 1:28 pm, surveyors observed one Cepheid GeneXpert analyzer (Serial Number: 120006103) being utilized for patient testing. 2. Review of QC records revealed a lack of documentation of external QC results for each day of testing on the Cepheid GeneXpert analyzer from the start of patient testing 08/28/2025 through survey date, 01/21/2026. 3.Review of laboratory policies and procedures revealed policies titled, "MOL.09: Cepheid Xpert Xpress Cov-2 Plus", "MOL.07: Cepheid Xpress Strep A" and "MOL.02: Cepheid Xpert Xpress Cov-2/Flu/ RSV plus (4Plex) which all state under, "Quality Control", "A. Quality control consists of both internal and external controls 2. External controls are purchased from separate vendor and tested in the following frequencies: c. when problems (storage, operator, instrument or other) are suspected or identified." 4. Interview with the TS on 01/21/2026 at 10:15am stated, the laboratory did not run external daily control materials because they thought the IQCP was completed and authorized by the LD. 5. Review of laboratory QC policies and procedures the laboratory failed to have a complete Individual Quality Control Plan (IQCP) Cov-2/ FLU[A&B]/ RSV plus (4-Plex), Xpert Xpress CoV-2 plus, and Xpress Strep A testing on the Cepheid GeneXpert analyzer (See D5445-A). 6. Review of patient reports revealed five patients' results were reported when daily external control results were not recorded: Test Date: Patient Id: Test: 09/10/2025 GE15300231 4-Plex+ Covid 10 /29/2025 GE15336733 4-Plex+ Covid 11/14/2025 GE14435646 Strep A 12/16/2025 GE15336445 4-Plex+ Covid 01/06/2026 GE12631592 4-Plex+ Covid 7. Additional interviews with GS #1, GS #2 and the TS on the second date of survey, 01/21/2026, at 03:54 pm, confirmed the laboratory failed to ensure external QC materials were run each day of testing and before reporting patient test results for Cov-2/ FLU[A&B]/ RSV plus (4-Plex), Xpert Xpress CoV-2 plus, and Xpress Strep A on the Cepheid GeneXpert analyzer as required per 493.1256, affecting five patient results.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: A. Based on a tour of laboratory, review of laboratory records, IQCP documentation, laboratory non-waived test volume worksheet, lack of documentation and interviews with the general supervisors (GS#1 and GS#2) and the technical supervisor (TS); the laboratory failed to develop a complete Individual Quality Control Plan (IQCP) for three of three testing cartridges for Cov-2/ FLU[A&B]/ RSV plus (4-Plex), Xpert Xpress CoV-2 plus, and Xpress Strep A in the specialty of microbiology on the Cepheid GeneXpert analyzer (Serial Number: 120006103) from start of testing in August 2025 through the date of survey, 01/21/2026, affecting 4589 patients. Findings include: 1. Direct observation during a tour of the laboratory on survey date, 01/20 /2026, at 1:28 pm, surveyors observed a Cepheid GeneXpert analyzer (Serial Number:

	120006103) being utilized for patient testing with three test cartridges, Cov-2/ FLU [A&B]/ RSV plus (4-Plex), Xpert Xpress CoV-2 plus, and Xpress Strep A. 2. Interviews with GS #1, GS #2 and the TS during a tour of the laboratory on survey date, 01/20/2026, at 1:28 pm, confirmed the laboratory utilized an IQCP for testing on the Cepheid GeneXpert analyzer. 3. Review of the laboratory IQCP documentation found the laboratory lacked a complete IQCP for three of three test cartridges performed (Cov-2/ FLU[A&B]/ RSV plus (4-Plex), Xpert Xpress CoV-2 plus, and Xpress Strep A) on the Cepheid GeneXpert analyzer. The IQCP documentation failed to address the following required components of an IQCP for each cartridge: a. Quality Control Plan - No plan identified. b. Quality Assessment - No plan identified. 4. Review of the laboratory non-waived test volume worksheet indicated 4,589 patient tests were performed on the Cepheid GeneXpert for 4-Plex, SARS Covid 2, RSV, Strep A and Influenza A&B from August 2025 through December 2025. 5. Interview with the TS on the date of survey, 01/20/2026, at 3:10 pm confirmed the laboratory failed to have a complete IQCP for three of three test cartridges performed on the Cepheid GeneXpert analyzer (Serial Number: 120006103) from start of testing in August 2025 through the date of survey, 01/21/2026, affecting 4589 patients. B. Based on tour of laboratory, review of laboratory records, IQCP documentation, laboratory non-waived test volume worksheet, lack of documentation and interviews with the general supervisors (GS #1 and GS #2) and the technical supervisor (TS); the laboratory failed to develop a Individual Quality Control Plan (IQCP) for three of three analytes (Trichomonas vaginalis, Gardnerella vaginalis and Candida species (vaginitis panel)) tested in the specialty of microbiology on two BD Affirm VPII analyzers, A (Serial number: 606016) and B (serial number: 605026) from start of testing August 2025 through the date of survey 01/21/2026, affecting 237 patients. Findings include: 1. Direct observation during a tour of the laboratory on the first date of survey, 01/20/2026, at 1:28 pm, surveyors observed two BD Affirm VPIII analyzers, A (Serial number: A606016) and B (serial number: A605026) being utilized for patient testing. 2. Review of the IQCP documentation for VPII Microbial Test (vaginitis panel) on the BD Affirm analyzers A & B found the IQCP failed to address the following required components of an IQCP: a. Risk Assessment - Failed to address the specimens, test system, reagents, and environment testing personnel and cover the entire test process from pre-analytical, analytical, and post analytical processes as well as supporting documentation. b. Quality Control Plan - No plan identified. c. Quality Assessment - No plan identified. 3. Review of the laboratory non-waived test volume worksheet indicated 237 patient tests were performed on two of two the BD Affirm analyzers instruments A and B for Trichomonas vaginalis, Gardnerella vaginalis and Candida species from August 2025 through December 2025. 4. Interview with the TS on the first date of survey, 01/20/2026, at 3:10 pm confirmed the laboratory failed to have a develop an IQCP for three of three analytes of the vaginitis panel (Trichomonas vaginalis, Gardnerella vaginalis and Candida species) testing in the specialty of microbiology on two of two BD Affirm VPII analyzers A (Serial number: A606016) and B (serial number: A605026) from start of testing August 2025 through to date of survey 01/21/2026, affecting 237 patients.