Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2221266	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Johns Hopkins Advanced Clinical Chemistry Diag Lab	600 N Wolfe Street Meyer Basement Rm 154, Baltimore, MD	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory director (LD), the laboratory did not have a procedure for verifying the accuracy of the multiplex oral fluid SARS-CoV-2 IgG assay at least twice annually as required in 493.1236(c)(1). During the onsite survey on 12/14/2023 at 3:30 PM, the LD confirmed that there was no procedure to verify the accuracy of the multiplex oral fluid assay at least twice annually.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the laboratory director (LD), the laboratory failed to provide a client service manual with written pre-

	analytical instructions for clients to follow when collecting, storing, and submitting specimens for analysis. Findings: 1. Review of the policies and procedure manuals showed that the laboratory did not have written instructions available to their clients that included patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source, specimen storage and preservation, conditions for specimen transportation, specimen processing, specimen acceptability and rejection, specimen referral and how to maintain the patient log book at the offices. 2. During the survey on 12/14/2022 at 3: 30 PM the LD confirmed that the laboratory did not have written pre-analytical instructions available to their clients for the collection and transportation of the specimens to the reference laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on remote review of the procedure and final report example and email communication with the laboratory director (LD), the laboratory's procedures did not include all required elements. Findings: 1. The laboratory had two procedures for performing IgG analysis on oral fluid: 1) C0001 Multiplex Oral Fluid SARS-CoV-2 IgG Assay for the MagPix and 2) C0003 Multiplex Oral Fluid SARS-CoV-2 IgG Assay for the ELISA. 2. Neither procedure included requirements for specimen acceptability and rejection. 3. Procedure C0001 did not include a description of the standards used or instructions for how to prepare the standards. 4. Neither procedure included a description of the quality control material used. 5. Procedure C0001 did not include batch acceptance criteria for quality controls. 6. Neither procedure included batch acceptability criteria for standards. 7. Neither procedure described what corrective actions to take when the standards or quality control did not meet acceptance criteria. 8. The final report example included "Positive," "Negative," and "Indeterminate" results. Neither procedure included instructions for how to interpret and report patient results. 9. The final report example stated that an indeterminate result was due to insufficient total IgG detected. Neither procedure defined how total IgG was measured or what criteria was used to determine insufficient quantities. 10. The laboratory sent batch results to submitting study groups. Neither procedure

	included instructions for reporting batch results to the submitting study groups. 11. In an email response received on 02/14/2023, the LD confirmed that batch acceptance criteria for quality controls and standards and instructions for interpreting and reporting assay results were not located in other procedures. II. Based on remote review of the procedure and final report example, the laboratory's procedure did not include instructions for reporting results to the submitting study group. Findings. 1. The procedure C0002 Cobas e411 Elecsys Anti-SARS-CoV-2 Assays was reviewed. 2. The final report example was a spreadsheet with columns for the patient identification number, collection date, receipt date, report date, and results. During the onsite survey on 12/14/2022 the testing person stated that new results were added onto the same spreadsheet that was shared with the submitting study group. 3. The procedure did not include instructions for reporting patient results to the submitting study group.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the "cobas e 411 analyzer Maintenance Log " and interview with the general supervisor (GS), the laboratory failed to follow the manufacturer's instructions when performing maintenance on the cobas e 411 general immunology analyzer. Findings: 1. The "cobas e 411 analyzer Maintenance Log" worksheets from August 2020 through November 2022 were reviewed. 2. The worksheet requires the laboratory to replace the pinch valve tubing on a monthly basis. The worksheet includes the following statement "Monthly when using Sample Reception Mode or every two months when not using Sample Reception Mode." 3. The worksheets showed that the replacement of the "pinch valve tubing" had not been replaced for over 28 months. 4. During the survey on 12/14/2022 at 3:30 PM the GS confirmed that the laboratory had not followed the manufacturer's instructions and changed the "pinch valve tubing" at least every two months while performing patient testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: I. Based on remote review of the internal audit procedure and completed audit forms, the laboratory failed to document the performance of internal audits at the frequency defined in the procedure. Findings: 1. The laboratory performed two assays: 1) Cobas e411 Elecsys Anti-SARS-CoV-2 (Cobas) and 2) Multiplex Oral Fluid SARS-CoV-2 IgG (Oral Fluid). 2. The procedure titled "A0005 Internal Audit" stated that a review of pre-analytical, analytical, and post analytical sections of the laboratory were "to take place every 3 months." Each of the three sections had its own audit form located

	in the appendices 7.1, 7.2, and 7.3, respectively. 3. The procedure stated that personnel documents, including training and competency assessments, were to be reviewed annually and included a "Personnel Records Audit Form" located in appendix 7.5. 4. The procedure stated that an initial study audit was to be performed "within the first month after study startup" and a periodic study audit "should be performed at least every 6 months for active studies." Both audit types were to be documented on the "Study Audit Form" located in appendix 7.7. 5. A request for the laboratory to send any internal audits performed for the two assays was emailed on 12 /21/2022. 6. Documents received on 01/23/2023 included a "Pre-Analytical Audit Form" (appendix 7.1) completed on 12/06/2022 and a "Study Audit Form" (appendix 7.7) from two periodic study audits performed on 06/10/2022 and 12/06/2022, all for the Cobas assay. 7. No analytic, post-analytic, personnel, or Oral Fluid study audits were submitted. II. Based on remote review of the Quality Management Plan (QMP) and meeting minutes, the laboratory failed to document attendance as stated in the QMP. Findings: 1. Section 5.1.1 of the QMP stated that quality meetings were to be held weekly and meeting minutes documented on the meeting minutes form in appendix 7.2, which included a section at the bottom for the laboratory director's signature and date. 2. The procedure stated that the "Meeting Attendance Form (Appendix 7.3) will be printed out and signed by all staff members attending the meeting." 3. A request for the laboratory to send a couple examples of the weekly meetings was emailed on 12/21/2022. 4. An electronic copy of the meeting minutes from 05/26/2022 and 10/27/2022 was received on 01/23/2023 that did not include any signatures. 5. A request for the laboratory to send a copy of the meeting minutes that were reviewed and signed as well as the completed Meeting Attendance Forms was emailed on 01/27/2023. 6. The electronic copies of the meeting minutes from 05/26 /2022 and 10/27/2022 were received on 02/14/2023 both signed by the laboratory director on 02/09/2023, indicating that the forms were not signed at the time of the meetings. 7. The Meeting Attendance Forms signed by all attending staff members were not received.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the "Training and Competency Assessment" procedure, and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure that the worksheets provided in the training manual were used to document the initial training of the testing personnel who performed high complexity testing. Findings: 1. The laboratory's generic "Training and Competency Assessment" procedure states that the QM (Quality Management) Coordinator is responsible for: "Capture of training and competency information for employees and ensuring that this documentation is appropriate." The documentation is to be recorded on the document number "A0004" which is included in the "Training and Competency Assessment" procedure. The QM Coordinator is the qualified GS. 2. The laboratory started testing in August 2020. The "Laboratory Personnel Report (CLIA) (CMS-209)" form lists four testing personnel. The training records for 2020 through 2022 were reviewed.

	There were no initial training, six month or annual evaluation records for the four testing personnel listed who performed testing on the Roche e411 and Magpix (Immunoassay analyzers). 3. During the survey on 12/14/2022 at 3:30 PM the LD confirmed that the laboratory records did not include initial training, six month or annual evaluation records of the four testing personnel listed on the CMS-209 who performed testing on the Roche e411 and Magpix analyzers.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on remote review of procedures and completed batch worksheets, the completed batch worksheets were missing information and not completed when testing was performed. Findings: 1. The laboratory had two procedures for performing IgG analysis on oral fluid: 1) C0001 Multiplex Oral Fluid SARS-CoV-2 IgG Assay for the MagPix and 2) C0003 Multiplex Oral Fluid SARS-CoV-2 IgG Assay for the ELISA. 2. Each procedure had a batch run form as appendix 8.1 and a plate map template as appendix 8.2 which were slightly different depending on each procedure. 3. Procedure C0001 stated that appendix 8.1 "must be completed with each batch of samples" and procedure C0003 stated that the plate map template "must be completed with each batch of samples." 4. An example of the batch run form and a plate map template from a single test batch was requested for review via email on 01/27/2023. 5. Documentation received on 02/14/2023 included the run form (appendix 8.1) from procedure C0003 and the plate map template (appendix 8.2) from procedure C0001. 6. The run form showed sample preparation performed on 10/26/2022, testing performed on 12/07/2022, and data analysis performed on 01/04/2023. A note initialed by the testing person and dated 02/08/2023 stated that the dates entered into the form were backdated, indicating that the form was not filled out when the testing was performed. 7. The completed plate map template that was received was missing the "Plate name," "Date performed," and lot number and expiration date for "PBS-T." 8. The completed plate map template that was received included rows for the lot number and expiration dates for the reagents "Standard Set," "Low Positive Control," and "Gen N," which were not included in the plate map template located in procedure C0001.