Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2034851	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ayass Laboratory, Llc	8501 Wade Blvd Suite 750, Frisco, TX	

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	Laboratory representatives were present at the entrance conference conducted 05/03 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 05/05 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the ACCESS SARS-CoV-2 IgM and ACCESS SARS-CoV-2 IgG test instructions for use, patient records, and interview with facility personnel, the laboratory failed to report SARS-COV-2 antibody test results as required for 79 of 79 days testing was performed between February 1, 2021 and May 4, 2021. The findings included: 1. Based on review of the ACCESS SARS-CoV-2 IgM test instructions for use (Ref C58957), under Intended Use on page 2 of 12, the instructions state "Laboratories within the United States and its territories are required to report all

	results to the appropriate public health authorities." 2. Based on review of the ACCESS SARS-CoV-2 IgG test instructions for use (Ref C69057), under Intended Use on page 2 of 12, the instructions state "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 3. Based on review of the laboratory's policy "DXI 600 Procedures Manual (3)", on page 1 of 11 under Intended Use, the policy states "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." This procedure was signed by the laboratory director on 11-01-2020. 4. Based on review of patient records, the laboratory performed patient tests 79 days between February 1, 2021 and May 4, 2021. 3 days in May 2021 26 days in April 2021 26 days in March 2021 24 days in February 2021 5. In an interview on May 4, 2021 at 10:38 hours in the office, General Supervisor 1 (as listed on the CMS-209 Laboratory Personnel Report) stated the laboratory had not reported ACCESS SARS-CoV-2 IgM or ACCESS SARS-CoV-2 IgG test results to HHS. General Supervisor 1 stated "we are uploading the PCR tests daily to the DSHS portal, but we do not upload the antibody tests."
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, hematology quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions for QC failures for 11 of 23 runs in 2020 (random review 11/2020 through 12/2020). Findings: 1. Review of the laboratory's policy titled "Whole Blood on the Sysmex XN-L 550" revealed: "V. QUALITY CONTROL ... Quality Control should be run in accordance with regulatory requirements. For the BeyondCare Quality Monitor program, a minimum of 2 levels of controls are needed to be run at least once every 24 hours. It should be noted that for troubleshooting purposes, additional control runs may be necessary. The BeyondCare Quality Monitor program is a toll [sic] that will help guide the end user of the next action. All troubleshooting actions are logged in the Activity Log." 2. Review of Sysmex XN-L 550 QC records revealed the laboratory failed to document corrective actions for QC failures in 2020 on the following dates and times: QC Level 1 control lot #02981401, expiration date 02/02/2021 QC Level 2 control lot #02981402, expiration date 02/02/2021 QC Level 3 control lot #02981403, expiration date 02/02/2021 11/05/2020 Level 1 13:03 hours QC failed for RDW-SD 13:15 hours QC was repeated and passed 11/06/2020 Level 2 control 11:46 hours QC failed for MPV 12:04 hours QC was repeated and passed 11/08/2020 Level 3 control 12:50 hours QC failed for RBC, PLT 13:04 hours QC was repeated and passed 11/15/2020 Level 3 control 01:00 hours QC failed for PLT 01:05 hours QC was repeated and passed 11/17/2020 Level 1 control 12:03 hours QC failed for LYMPH#, LYMPH% 12:14 hours QC was repeated and passed Level 2 control 08:

	50 hours QC failed for PLT 08:54 hours QC was repeated and passed 11/22/2020 Level 2 control 09:23 hours QC failed for PLT 09:26 hours QC was repeated and passed 11/25/2020 Level 1 control 17:28 hours QC failed for PLT 17:30 hours QC was repeated and failed for WBC, NEUT# 17:38 hours QC was repeated and failed for PLT 17:40 hours QC was repeated and passed Level 2 control 19:32 hours QC failed for MCV, MONO#, MONO% 19:35 hours QC was repeated and passed 12/07 /2020 Level 1 control 20:25 hours QC failed for MCV 20:29 hours QC was repeated and failed for HCT, MCV 20:31 hours QC was repeated and passed 12/10/2020 Level 3 control 18:45 hours QC failed for HCT, MCHC 18:48 hours QC was repeated and passed 12/29/2020 Level 1 control 21:07 hours QC failed for MCV 21:11 hours QC was repeated and failed for MCV 21:14 hours QC was repeated and failed for MCV 21:21 hours QC was repeated and passed Level 2 control 19:48 hours QC failed for HCT, MCHC 19:53 hours QC was repeated and failed for HCT, MCHC 19:56 hours QC was repeated and passed 12/30/2020 Level 3 control 19:22 hours QC failed for RDW-SD 19:28 hours QC was repeated and passed The laboratory failed to document corrective action for the above QC failures. 3. During an interview on 05/04/2021 at 12:10 hours, the Technical Consultant stated that there was no corrective action log for hematology QC failures and corrective actions were to be documented on the Sysmex XN-L 550 analyzer by testing personnel, but none were documented. This confirmed the above findings. Word Key: RDW-SD- red blood cell distribution width MPV- mean platelet volume RBC- red blood cell PLT-platelet LYMPH#- lymphocyte count LYMPH%- lymphocyte percentage NEUT#- neutrophil count NEUT%- neutrophil percentage WBC- white blood cell MCV- mean corpuscular volume HCT- hematocrit MONO#- monocyte count MONO%- monocyte percentage MCHC- mean corpuscular hemoglobin concentration