

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1096437	(X3) Date Survey Completed 04/13/2022
Name of Provider or Supplier Carol N Abalihi Md Pa	Street Address, City, State 12350 Paseo Nuevo Dr, El Paso, 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	As a result of the CLIA onsite survey conducted April 13th and 14th, 2022, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 42 CFR part 493: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems;
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, the CMS 209 Laboratory Personnel Report form, laboratory policies and procedures, and interview with facility personnel, the laboratory failed to ensure policies and procedures were established to assess competency of two of two testing personnel. Findings included: 1. Review of personnel records and the CMS 209 form revealed the laboratory employed two testing personnel and had not yet assessed competency on either testing persons. 2. During an interview on 4/13/2022 at 10:15 am, Testing Person 1 confirmed the laboratory had not established written policies and procedures for assessing competency. Key: CMS - Center for Medicaid and Medicare Services</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the</p>

overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on surveyor observations, review of policies and procedures, review of quality control records, patient records, verification studies, and interview with facility personnel, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Refer to D5449, D5421, and D5783.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(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 a review of quality control (QC) instructions for use, instrument data, and confirmed in interview, the laboratory failed to have a policy for the establishment or verification for the mean and ranges of two levels of QC for the Alfa Wasserman chemistry analyzer for 6 months since its installation in November 2021. The findings include: 1. Review of the Alfa Wassermann Chemistry control instructions for use (IFU) and instrument printouts had the following acceptable ranges for each analyte. Refer to D5469. 2. Surveyor queried 4/12/2022 at 15:30 hours, in the conference room, for a policy for the verification and establishment of QC means and ranges for the Alfa Wasserman chemistry analyzer, and none was provided. 3. In an interview on 4/12/2022 at 14:05 hours, in the conference room, testing person 2 confirmed that the laboratory did not have a policy for the establishment or verification of QC means and ranges for the Alfa Wasserman chemistry analyzer. .

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor observations, review of temperature records, and interview with facility personnel, the laboratory failed to monitor the temperature and humidity in the laboratory for three of three months between January 2022 and March 2022 and failed to ensure frozen reagents and test supplies were stored appropriately for ten of eleven days in April 2022. The findings included: 1. At 15:24 hours on 4/12/2022, the surveyor observed two LabTurbo AIO Covid-19 RNA testing kits stored in the freezer. The temperature requirements were to store at -20C. 2. Based on review of

the freezer temperature records, the freezer did not achieve -20C in the ten of eleven days reviewed in April 2022. 04/01/2022 -17C 04/02/2022 -18C 04/03/2022 -17C 04/04/2022 -17C 04/05/2022 -18C 04/06/2022 -19C 04/07/2022 -19C 04/08/2022 -20C 04/09/2022 -19C 04/10/2022 -18C 04/11/2022 -17C 3. In an interview at 15:24 hours on 4/12/2022, Testing Persons 1 and 2 confirmed the freezer had not continuously provided temperatures of -20C. 4. In an interview at 10:15 hours on 4/13/2022 in the laboratory, Testing Persons 1 and 2 confirmed the laboratory had not taken temperature and humidity readings in the main laboratory space.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer instructions for verification protocols, the laboratory's verification studies for the hematology analyzer, and interview with facility personnel, the laboratory failed to verify patient normal ranges for one of one hematology analyzer in use since January 2022. The findings included: 1. Based on review of the Sysmex document "Method Verification Protocols", under Section 3, the document stated the following: "It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Reference Range Verification (See Resource Manual). Reference Range Study (for Customer Reference only) Reference ranges describe analyte levels associated with persons who are considered "healthy". Multiple factors can influence a reference range including, population selection (geography and demographics) and specimen collection and handling. Assuming the study that resulted in the current reference range. was performed correctly, that the population has not changed, and the new analyzer is determined to be comparable (correlation), a study to verify the current reference ranges with the new analyzer is appropriate. The outcome of this study either verifies the current reference range or determines whether a new reference range needs to be established. A. Sample Selection 1. Use your current reference ranges for the CBC, differential and reticulocyte parameters, if applicable, and your established criteria for "healthy" individuals to select samples. For example, normal donors may be defined as ones who: a. Have no clinical evidence of a medical disorder known to affect the CBC, differential and reticulocyte counts. b. Have had no recent episode of bleeding or infection. c. Have CBC, differential and reticulocyte counts within the current reference ranges. d. Healthy individuals selected should reflect the laboratory's patient population, including both male and female of an established age range. Separate reference ranges based on age may be necessary for pediatric or geriatric populations. 2. The sample size for this study is dependent upon your laboratory's policy and procedure for new analyzer implementation. Select at least 25 to 50 samples. A larger sampling, however, improves the confidence of the statistics generated from the study.

2. Based on review of the analytic records, the accuracy, precision, and reportable range were verified in January 2022. There were not records available for verification of patient normal ranges.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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--
At least once a day patient specimens are assayed or examined perform the following for--
Each qualitative procedure, include a negative and positive control material; (g)
The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on quality control records, patient results, and interview, the laboratory failed to run quality control each day of patient testing for 29 of 29 days testing was performed between February 22, 2022 and April 6, 2022 for 142 patient specimens tested on the Quidel Triage MeterPro for TOX Drug screen testing. The findings include: 1. Review of quality control records for the Quidel Triage MeterPro for TOX Drug Screen testing had QC every day of patient testing from January 20th 2022 to February 21st 2022, after which QC was only performed on March 22 and 30th, 2022, and April 8th 2022. 2. Review of patient TOX Drug Screen results for the six weeks since February 21, 2022 had the following 142 patients ran without control procedures being run prior to testing. February 2022: 30 Patients Test Date: Patient ID 2/22/2022: GA092389 2/22/2022: DV058176 2/22/2022: ST012075 2/23/2022: CJ120547 2/23/2022: CV062288 2/23/2022: HV030446 2/23/2022: MM072753 2/23/2022: RC122688 2/23/2022: CJ122003 2/23/2022: CM112883 2/23/2022: SM091062 2/23/2022: SX070901 2/24/2022: DR4442 2/24/2022: BE062384 2/24/2022: GO021154 2/24/2022: KM022555 2/24/2022: KD101957 2/24/2022: MM81861 2/24/2022: VS052296 2/24/2022: OD070260 2/24/2022: PC122462 2/25/2022: RA011402 2/25/2022: RD4549 2/25/2022: MC080156 2/25/2022: AC092230 2/25/2022: OT020147 2/28/2022: AM050754 2/28/2022: GJ080942 2/28/2022: LM121165 2/28/2022: PT100446 March 2022: 98 Patients Test Date: Patient ID 3/1/2022: AP71357 3/1/2022: HC120872 3/1/2022: OM070148 3/1/2022: MM092455 3/1/2022: CT092548 3/2/2022: MC011059 3/2/2022: ML05061974 3/2/2022: RM071547 3/2/2022: CI110752 3/2/2022: GK071702 3/3/2022: YD092391 3/3/2022: CD051357 3/3/2022: CC120954 3/3/2022: GM12145 3/3/2022: CD110554 3/4/2022: CG07091963 3/4/2022: EC112347 3/4/2022: GL31659 3/4/2022: DR102444 3/4/2022: HJ082552 3/4/2022: DA060301 3/7/2022: ED010314 3/7/2022: PT021647 3/7/2022: SD013152 3/7/2022: ES6864 3/7/2022: GP51661 3/8/2022: SJ081004 3/8/2022: RD082854 3/8/2022: PB082064 3/8/2022: MS060177 3/9/2022: MS32597 3/9/2022: MR-090363 3/9/2022: AL-052878 3/9/2022: ML013048 3/9/2022: LJ-21557 3/9/2022: DV-020654 3/9/2022: KP031554 3/10/2022: CV062474 3/10/2022: MO032057 3/10/2022: SD123046 3/10/2022: LL092395 3/10/2022: MR082063 3/11/2022: PG031857 3/11/2022: CR102284 3/11/2022: FR110486 3/11/2022: CM021141 3/11/2022: LJ102989 3/11/2022: GV101049 3/11/2022: LM121165 3/14/2022: GI112678 3/14/2022: CJ112969 3/14/2022: RD101288 3/14/2022: VA112263 3/14/2022: RO052681 3/15/2022: MR042572 3/15/2022: SC022057 3/15/2022: AP052570 3/15/2022: AKC072465 3/16/2022: LI071602 3/16/2022: MC020262 3/16/2022: VI110752 3/16/2022: LVJ010949 3/16/2022: SP062251 3/16/2022: SN120749 3/16/2022: OSG032465 3/17/2022: GA030707 3/17/2022: BA082434 3/17/2022: PHM070461 3/17/2022: TT100192 3/17/2022: ST72154 3/17/2022: CB090173 3/20/2022:

CCE060352 3/20/2022: RS011470 3/20/2022: DK090600 3/20/2022: CC010249 3/21/2022: ST012075 3/21/2022: CV092249 3/21/2022: ST033041 3/23/2022: SM091062 3/23/2022: GE072363 3/24/2022: TJ102154 3/24/2022: GG-101751 3/24/2022: RE120957 3/24/2022: VC-062288 3/24/2022: GS091145 3/24/2022: KM032555 3/24/2022: JA-122773 3/24/2022: LM021384 3/24/2022: CJ-091956 3/24/2022: GM-012145 3/24/2022: AM071547 3/25/2022: VS052296 3/25/2022: AP071357 3/28/2022: LA-041977 3/28/2022: RG022555 3/28/2022: CA030450 3/29/2022: PH062751 3/29/2022: GA-042577 April 1-6th 2022: 14 Patients Test Date: Patient ID 4/1/2022 : HMN052691 4/1/2022: BJ-101779 4/1/2022: CV092249 4/4/2022: CD110554 4/4/2022: RE012455 4/4/2022: BL-101646 4/4/2022: GR071592 4/5/2022: GJ-103006 4/5/2022: OT-020147 4/5/2022: CC-120954 4/5/2022: CD-051357 4/6/2022: LJ100482 4/6/2022: GK071702 4/6/2022: DV020654 3. In an interview on 4/12/2022 at 09:25 hours, in the conference room, testing person 2 confirmed that QC was not performed every day of patient testing past February 21, 2022 for TOX Drug Screen testing. .

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on a review of quality control (QC) instructions for use, instrument data, and confirmed in interview, the laboratory failed to verify the means and ranges for two levels of QC for the Alfa Wasserman chemistry analyzer for 6 months since its installation on November 2021. 1. Review of the Alfa Wassermann Chemistry control instructions for use (IFU) and instrument printouts had the following acceptable ranges for each analyte: Level 1 Chemistry Control Lot 1501UNCM, Expiration 11/28/2024 Analyte: IFU Range - Instrument Range PHOS:2.8 - 3.8 2.9 - 3.7 MG: 2.0 - 2.8 2.2 - 2.8 NA: 123.9 - 151.5 128.5 - 146.9 K: 3.55 - 4.55 3.72 - 4.38 CL: 96.1 - 117.5 99.7 - 113.9 CA: 8.6 - 10.6 9.0 - 10.2 AST: 39 - 59 42 - 56 ALP: 53 - 79 54 - 75 GLU: 88 - 108 86 - 98 TBILI:1.2 - 2.0 1.3 - 1.9 TP: 4.1 - 4.9 4.2 - 4.8 ALB: 2.5 - 3.3 2.6 - 3.2 CREAT:1.48 - 2.08 1.58 - 1.98 UA: 4.3 - 6.1 4.4 - 5.6 CHOL: 101 - 123 102 - 116 TRIG: 81 - 111 84 - 104 HDL: 35 - 47 34 - 42 ALT: 43 - 64 46 - 60 CO2: 11.9 - 17.9 11.7 -15.5 Level 2 Chemistry Control Lot 1166 UECM, Expiration 11/28/2024 Analyte : IFU Acceptable Range - Instrument Acceptable Range PHOS: 6.0 - 8.2 6.3 - 7.9 MG: 4.1 - 5.5 4.4 - 5.4 NA: 110.5 - 135.1 114.6 - 131.0 K: 7.23 - 8.23 7.40 - 8.06 CL: 72.6 - 88.8 75.3 - 86.1 CA: 10.9 - 13.3 11.3 - 12.9 AST: 171 - 257 185 - 243 ALP: 320 - 480 347 -453 GLU: 279 - 341 270 -308 TBILI: 4.3 - 6.4 4.6 - 6.0 TP: 6.9 - 8.5 7.2 - 8.2 ALB: 3.9 - 5.3 4.1 - 5.1 CREAT: 6.33 - 8.57 6.71 - 8.19 UA: 7.9 - 11.1 8.3 -10.5 CHOL: 177 - 217 177 - 203 TRIG: 154 - 212 159 - 197 HDL: 62 - 82 63 -

77 ALT: 111 - 167 121 - 157 CO2: 24.4 - 36.6 23.8 - 31.8 2. Surveyor queried 4/12/2022 at 15:30 hours, in the conference room, for a policy for the verification of QC means and ranges for the Alfa Wasserman chemistry analyzer, and none was provided. Testing person (TP) 2 stated they occasionally adjust the means and acceptable range from the QC datasheets. 3. In an interview on 4/12/2022 at 14:05 hours, in the conference room, testing person 2 confirmed that the laboratory did not verification of QC means and ranges for the Alfa Wasserman chemistry analyzer. .

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

. Based on review of quality control (QC) records, patient test results, and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable QC for the Alfa Wasserman chemistry analyzer for QC failures that could not be resolved with repeat testing for 28 out of 28 patients for 30 days reviewed in 2021 and 2022. 1. Review of laboratory QC and patient testing records, for the Alfa Wasserman chemistry analyzer, had the following six analyte failures that could not be resolved with repeat testing and 28 patients that were not evaluated to the last acceptable QC in November and December 2021, and February and March 2022. On 11/23/2021, level 1 QC was outside the laboratory's acceptable limits for CO2 with a corrective action statement of "rerun after cleaning probe". CO2 QC was within limits at 12:03 pm. Five patients testing for the analyte CO2 since the last acceptable run on 11/22/2021 were: RD040442 JH090354 MM09241955 VC062288 DJ07131980 On 11/30/2021, level 1 QC was outside of the laboratory's acceptable limits for glucose (GLU) with a corrective action statement of "Clean probe, recalibrate". GLU QC was within limits at 10:44 am. Six patients tested for the analyte GLU since the last acceptable run on 11/29/2021 were: HR02081964 BZC09011973 JC11212003 BAG10141974 RP02111973 EJC05181953 On 12/10/2021, level 2 QC was outside of the laboratory's acceptable limits for creatinine (CREAT) with a corrective action statement of "recalibrate". CREAT QC was within limits at 10:15 am. Two patients tested for the analyte CREAT since the last acceptable run on 12/9/2021 were: 1120921053 1120921054 On 2/15/2022, level 1 QC was outside of the laboratory's acceptable limits for aspartate transferase (AST) with a corrective action statement of "clean probe path". AST QC was within limits at 11:07 am. Two patients tested for the analytes AST since the last acceptable run on 2/14/2022 were: 1021422085 1021422084 On 3/10/2022, level 1 QC was outside of the laboratory's acceptable limits for triglyceride (TRIG) with a corrective action statement of "rerun after cleaning probe". TRIG QC was within limits at 11:38 am. Four patients tested for the analyte TRIG since the last acceptable QC on 3/9/2022 were: 1030922184 1030922183 1030922182 1030922181 On 3/15/2022, level 1 QC was outside of the laboratory's acceptable limits for triglyceride (TRIG) with a corrective action statement of "rerun after cleaning probe". TRIG QC was within limits at 09:10 am. Four patients tested for the analyte TRIG since the last acceptable

QC on 3/14/2022 were: 1030922194 1030922195 1030922196 1030922197 2. In an interview 4/12/2022 at 14:15 hours, in the conference room, testing person 2 confirmed that the laboratory did not evaluate patients to the last acceptable QC when there were QC failures that could not be resolved with repeat testing. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, surveyor observations, quality control records, corrective actions, and confirmed in interview, the laboratory failed to establish written policies and procedures to identify and correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings included: The laboratory failed to establish quality assessment procedures to identify, detect, and correct that the laboratory failed to have written procedures manual for all tests, assays, and examinations performed by the laboratory. Refer to D5401. The laboratory failed to establish quality assessment procedures to identify, detect, and correct that the laboratory failed to establish conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Refer to D5413. The laboratory failed to establish quality assessment procedures to identify, detect, and correct that the laboratory failed to run quality control each day of patient testing for specimens tested on the Quidel Triage MeterPro for TOX Drug screen testing. Refer to D5449. The laboratory failed to establish quality assessment procedures to identify, detect, and correct that the laboratory failed to evaluate all patient test results obtained since the last acceptable QC for the Alfa Wasserman chemistry analyzer for QC failures that could not be resolved with repeat testing for 28 out of 28 patients for 30 days reviewed in 2021 and 2022. Refer to D5783.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on surveyor observations, quality control policies and procedures, quality control records, patient records, and confirmed in interview, the laboratory director failed to ensure that quality control and quality assessment programs were established and maintained to identify, monitor, and correct failures in quality of testing as they occurred. Refer to D5449, D5469, D5783, and D5791.