Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2196666	09/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Lab Services, Pllc	3786 Fm 1488, Suite 150a, Conroe, 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	An unannounced revisit survey was performed on 10/28/2022. The laboratory was found to be in compliance with the CLIA conditions of participation and certification is recommended. STANDARD LEVEL DEFICIENCIES remain. ********** The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400- 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity; Laboratory Director Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 10/28/2022. D5209- I remains uncorrected Based on review of the laboratory plans of correction with a completion date of 10/16 /2022, review of laboratory's personnel records and staff interview, it was determined the facility failed to correct the deficiency and ensure documentation of competency

	assessment for one of one Clinical Consultants employed by the laboratory was completed. Findings included: 1. Review of the laboratory plans of correction with a completion date of 10/16/2022 revealed: "... the Laboratory Director will ensure all competencies are updated for every personeel (sic) type, such as Testing Personeel (sic), Technical Consultant, Clinical Consultant, General Supervisor, Laboratory Manager and Laboratory Director." 2. Review of laboratory's personnel records revealed the laboratory did not have documentation of competency assessment for its Clinical Consultant. 3. In an interview on 10/28/2022 at 0930 hours in the break room, the Laboratory Director confirmed the findings. ********** Based on review of the laboratory's submitted Form 209, review of laboratory's personnel records and staff interview, it was determined the laboratory failed to document competency assessment for one of one Clinical Consultants employed by the laboratory. Findings included: 1. Review of the laboratory's submitted Form 209 revealed the laboratory employed one Clinical Consultant. 2. Review of laboratory's personnel records revealed the laboratory did not have documentation of competency assessment for its Clinical Consultant. 3. In an interview on 09/19/2022 at 1105 hours in the break room, the Laboratory Director confirmed the findings.
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 laboratory's policies and procedures, surveyor's observations and staff interview, it was determined the laboratory failed to ensure received specimens were labeled as required for 6 of 6 specimen observed. Findings included: 1. Review of laboratory's policy "General Laboratory Information" (GEN-01, implemented 04/01 /2021) revealed: "D. SPECIMEN LABELING Specimens should be labeled with: the patients name, date of birth, date and time collected, and initials of the collector." 2. Surveyor's observations on 09/19/2022 at 1305 hours in the laboratory revealed 6 samples stored in the refrigerator awaiting testing. 3. Examination of the refrigerated samples revealed the samples did not include the following labeling requirements: Patient #1 Missing: Date/time of collection and collector's initials. Patient #2 Missing: Date/time of collection and collector's initials. Patient #3 Missing: Patient's first name, patient's date of birth, date/time of collection and collector's initials. Patient #4 Missing: Patient'sdate of birth and collector's initials. Patient #5 Missing: Patient's first name, patient's date of birth, date/time of collection and collector's initials. Patient #6 Missing: Patient's date of birth, date/time of collection and collector's initials 4. In an interview on 09/19/2022 at 1305 hours in the laboratory, the Laboratory Director, after examination of the refrigerated samples, confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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 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 review of the manufacturer's instructions, review of patient records, review of instruments' maintenance, quality control (QC), calibration documents, quality assessment (QA) documents and staff interview, it was determined the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to ensure its policies were followed for new policy implementation. Refer to D5401. 2. The laboratory failed to ensure specimen verification for adulterants was addressed. Refer to D5403. 3. The laboratory failed to ensure that calibration verification for the toxicology analyzer was performed every 6 months. Refer to D5439. 4. The laboratory failed to ensure QC was documented each day of patient testing. Refer to D5449. 5. The laboratory failed to ensure QA was maintained. Refer to D5791.
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 surveyor's observations, review of the laboratory's policies and procedures and staff interview, it was determined the Laboratory Director failed to follow laboratory's policy for signing each new policy and procedure into effect. Findings included: 1. Surveyor's observations on 09/19/2022 at 1130 hours in the break room revealed the laboratory's procedure manual contained a onetime approval sheet for all policies and procedures included in the manual. There was no Laboratory Director's signature on each individual policy or procedure included within the manual. 2. Review of the laboratory's policy "General Laboratory Information" (GEN-01, implemented on 04/01/2022) revealed: "6. The Laboratory Director will review, approve, and sign each procedure. " 3. In an interview on 09/19/2022 at 1130 hours in the break room, the Laboratory Director confirmed the findings.
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: Based on review of the manufacturer instructions for use for the toxicology reagents used by the laboratory, review of the laboratory's policies and procedures and staff interview, it was determined the laboratory failed to address specimen verification for adulterants prior to patient testing for 1 of 1 tests performed by the laboratory. Findings included: 1. Review of the manufacturer instructions for use for the Siemens Syva (EMIT II Plus Amphetamines Assay -9C122UL.4DS_G and EMIT II Plus Buprenorphine Assay - 10872256_B) toxicology reagents revealed: "Adulteration of the urine specimens may cause erroneous results. If adulteration is suspected, obtain another specimen." 2. Review of the laboratory's policies and procedures revealed the laboratory did not establish protocols for specimen verification for adulterant content. 3. In an interview on 09/19/2022 at 1030 hours in the break room, the Laboratory Director confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: An unannounced revisit was performed on 10/28/2022. D3439 - remains uncorrected Based on review of the laboratory plans of correction with a completion date of 10/16 /2022, review of the laboratory's calibration verification records for the Siemens

	EMIT II toxicology analyzer and staff interview, it was determined the facility failed to correct the deficiency and ensure calibration verification protocol, protocol component specifications and evaluation acceptability criteria were established and documented. Findings included: 1. Review of the laboratory plans of correction with a completion date of 10/16/2022 revealed: "The Laboratory Director will implement a calibration verification protocol every six months. This calibration verification plan will include testing a low mid and high value for each of the analytes that are currently being tested." 2. Review of the laboratory's calibration verification records for the Siemens EMIT II toxicology analyzer revealed calibration verification raw data was obtained since the last survey. However, calibration verification protocol, component specifications, acceptability criteria and data evaluation procedures were not defined nor documented. 3. In an interview on 10/28/2022 at 0955 hours in the break room, the Laboratory Director, after review of the data, confirmed the findings. ********** Based on review of the laboratory's calibration records for 2020 and 2021 for the Siemens EMIT II toxicology analyzer, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to establish and follow protocols for calibration verification for one of one analyzer used by the laboratory. Findings included: 1. Review of the laboratory's calibration records for 2020 and 2021 for the Siemens EMIT II toxicology analyzer revealed the laboratory used one calibrator per analyte, each time calibration was performed. 2. Review of the laboratory's policies and procedures revealed there were no protocols in place for each analyte's calibration verification on the Siemens EMIT II toxicology analyzer, at least every 6 months. 3. The laboratory was asked to provide documentation of calibration verification every 6 months and no such documentation was available for review by the time of survey exit. 4. In an interview on 09/19/2022 at 1400 hours in the break room, the Laboratory Director confirmed the findings.
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 review of the laboratory's maintenance and quality control (QC) records for January to September of 2022 for the Siemens EMIT II toxicology analyzer, review of the laboratory's patient test records and staff interview, it was determined the laboratory failed to document QC each day of patient testing for 2 of 26 days testing was performed. Findings included: 1. Review of the laboratory's maintenance records for January to September of 2022 for the Siemens EMIT II toxicology analyzer revealed the laboratory performed instrument maintenance as follows: 01/06/2022 06 /10/2022 01/13/2022 06/16/2022 02/03/2022 06/23/2022 02/10/2022 06/30/2022 02/17 /2022 07/11/2022 02/22/2022 07/12/2022 03/24/2022 07/28/2022 03/29/2022 08/04 /2022 04/07/2022 08/11/2022 04/13/2022 08/18/2022 04/22/2022 08/26/2022 05/05 /2022 09/01/2022 05/19/2022 09/08/2022 2. Review of the laboratory's QC records for January to September of 2022 for the Siemens EMIT II toxicology analyzer revealed QC was performed each day the maintenance was performed except on: 07 /11/2022 07/12/2022 3. Review of the laboratory's patient test records revealed the

	following patients were tested on the days QC was not documented: a. Patients tested on 07/11/2022: Date collected: 06/27/2022 Patient # 19 Patient # 23 Patient # 20 Patient # 24 Patient # 21 Patient # 25 Patient # 22 Patient # 26 Date collected: 06/28 /2022 Patient # 27 Date collected: 06/29/2022 Patient # 28 Patient # 36 Patient # 29 Patient # 37 Patient # 30 Patient # 38 Patient # 31 Patient # 39 Patient # 32 Patient # 40 Patient # 33 Patient # 41 Patient # 34 Patient # 42 Patient # 35 Patient # 43 b. Patients tested on 07/12/2022: Date collected: 07/01/2022 Patient # 1 Patient # 5 Patient # 2 Patient # 6 Patient # 3 Patient # 7 Patient # 4 Date collected: 07/06/2022 Patient # 8 Patient # 13 Patient # 9 Patient # 14 Patient # 10 Patient # 29 Patient # 11 Patient # 30 Patient # 12 Date collected: 07/07/2022 Patient # 25 Date collected: 07/08 /2022 Patient # 15 Patient # 18 Patient # 16 Patient # 24 Patient # 17 Date collected: 07/11/2022 Patient # 19 Patient # 23 Patient # 20 Patient # 26 Patient # 21 Patient # 27 Patient # 22 Patient # 28 Refer to patient test log attached. 4. In an interview on 09 /19/2022 at 1515 hours in the break room, the Laboratory Director, after review of the data, confirmed the findings.
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 policies and procedures, review of laboratory's quality assessment (QA) records for 2021 and 2022, and staff interview, it was determined the laboratory failed to document all analytic systems assessment activities as per its own policy for 16 of 16 months reviewed. Findings included: 1. Review of the laboratory's policy "General Laboratory Information" (GEN-01, implemented on 04/01/2022) revealed: "IV Program Authority: The laboratory quality management program consists of an organized, integrated system of statistics, continuous monitors, and critical indicators which encompass all important aspects of care." AND "4. Improve customer satisfaction by performing monthly QA/QI (quality improvement) reports to review any customer and physician complaint." AND "A quarterly QI report is prepared from information and statistics obtained from theses sources. The report is to be reviewed by the Laboratory Director and findings forwarded to the appropriate committees, if necessary." 2. Review of laboratory's QA /QI records for 2021 and 2022 revealed no documentation of quarterly review by the Laboratory Director as per policy for 16 of 16 moths reviewed. 3. In an interview on 09/19/2022 at 1130 hours in the break room, the Laboratory Director, after review of the data, confirmed the findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, review of a random patient test record and staff interview, it was determined the laboratory's final report failed to indicate 5 of 9 required components of a test report as per laboratory policy. Findings included: 1. Review of laboratory's policy "Laboratory Patient Reports" (GEN-18, implemented 04/01/2021) revealed: "The paper and electronic reports include the following elements: 1. Name and address of the testing laboratory. 2. Patient name, date of birth, sex, and identification number (Medical record number). 3. Name of the physician of record, or legally authorized person ordering tests, as appropriate. 4. Date and time of specimen collection. 5. Date and time results were released and initials of the person performing and reporting test(s) [available on internal report]. 6. Specimen source if applicable. 7. Test results with units of measurement if applicable. 8. Reference intervals, as applicable. 9. Comments, if applicable (includes specimen issues, patient meds etc..)" 2. Review of a random patient's test record (Patient # 30 tested on 07/11/2022 at 0906 hours) revealed the following 5 of 9 required report components were not included on the report: Name of the testing laboratory Patient's date of birth and identification number Name of the physician of record Date and time of specimen collection Comments for specimen issues (report had result of "Rejected" for the Amphetamines 500 analyte without further explanation) 3. In an interview on 09/19/2022 at 1145 hours in the break room, the Laboratory Director, after review of the data, confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of patient records, review of instruments' maintenance, quality control (QC), calibration documents, quality assessment (QA) documents and staff interview, it was determined the Laboratory Director failed to provide overall management and direction of the laboratory. Findings included: 1. Laboratory Director failed to ensure laboratory's quality control was maintained. Refer to D6020. 2. Laboratory Director failed to ensure laboratory's quality control was maintained. Refer to D6021. 3. Laboratory Director failed to ensure pertinent information required for interpretation is included on the final reports. Refer to D6026. 4. Laboratory Director failed to specify, in writing, the responsibilities and duties of laboratory's personnel. Refer to D6032.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, analyzer calibration and maintenance records, patient test records and staff interview, it was determined the Laboratory Director failed to ensure laboratory's quality control was maintained. Refer to D5403, D5439 and D5449.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assessment activity records and staff interview, it was determined the Laboratory director failed to ensure Laboratory's quality assessment was maintained. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of random patient test records and staff interview, it was determined the Laboratory Director failed to ensure pertinent information required for interpretation is included on the final reports. Refer to D5805.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

	processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form 209, review of the laboratory's policies and staff interview it was determined the Laboratory Director failed to specify, in writing, the responsibilities and duties of one of one Clinical Consultants employed by the laboratory. Findings included: 1. Review of laboratory's submitted Form 209 revealed the laboratory employed one Clinical Consultant. 2. Review of laboratory's policy Position Description Evaluation (GEN-20, implemented 04/01 /2021) describing laboratory personnel duties and responsibilities, revealed the Laboratory Director did not define Clinical Consultant's responsibilities and duties as required. 3. In an interview on 09/19/2022 at 1105 hours in the break room, The Laboratory Director confirmed the findings.