Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2087522	09/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Lab Houston Lp	9130 South Texas 6, Houston, 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	A recertification survey was performed on 9/1/21 and 9/2/21 The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists proficiency testing (PT) instructions, review of the laboratory's CAP's proficiency testing records from 2019 and 2020, and confirmed in interview, the laboratory failed to have documentation of evaluating proficiency testing results returned as 'educational challenge' by the proficiency testing agency for three of six PT events reviewed. The findings were: 1. A review of the CAP testing instructions (2020) revealed Code 26: Educational challenge: Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. Response to the CAP is not required." 2. Review of the CAP surveys from 2019 and 2020 revealed the following three of six surveys with no documentation of the self-evaluation per CAP instructions. UDC-C 2020 Forensic Urine Drug Test Confirmatory Fentanyl UDC-21 See note [26] UDC-22 See note [26] UDC-23 See note [26] UDC-24 See note [26] UDC-25 See note [26]

	UDC-26 See note [26] UDC-27 See note [26] UDC-28 See note [26] NorFentanyl UDC-21 See note [26] UDC-22 See note [26] UDC-23 See note [26] UDC-24 See note [26] UDC-25 See note [26] UDC-26 See note [26] UDC-27 See note [26] UDC-28 See note [26] UDC-B 2020 Forensic Urine Drug Test Confirmatory Fentanyl UDC-20 See note [26] NorFentanyl UDC-20 See note [26] UDC-A 2020 Forensic Urine Drug Test Confirmatory Fentanyl UDC-04 See note [26] NorFentanyl UDC-04 See note [26] Fentanyl UDC-01 See note [26] UDC-02 See note [26] UDC-03 See note [26] UDC-04 See note [26] UDC-05 See note [26] UDC-06 See note [26] UDC-07 See note [26] UDC-08 See note [26] NorFentanyl UDC-01 See note [26] UDC-02 See note [26] UDC-03 See note [26] UDC-04 See note [26] UDC-05 See note [26] UDC-06 See note [26] UDC-07 See note [26] UDC-08 See note [26] 3. An interview with the compliance specialist on 9/1/21 at 1422 hours via phone confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's policy, the laboratory's stability study, patient test results, and confirmed in an interview revealed the laboratory failed to meet the requirements for preanalytic systems. Refer to D5311-I, II, and D5317.
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: I. Based on the review of the manufacturer's instructions, laboratory's policies, the laboratory's records from 2019 to 2021, and confirmed in an interview revealed the laboratory failed to establish the specimen storage and preservation; specimen transportation; and acceptability criteria for one of one EUA approved test (Applied BiosystemsTaqPath COVID-19 Combo Kit) for the qualitative detection of SARS-CoV-2. The findings were: 1. Review of the laboratory's policy TaqPath COVID-19 Combo Kit approved by the laboratory director on February 1, 2021 under Samples and Controls revealed "Specimens can be stored at 4C for up to 72 hours after collection." 2. Review of TaqPath COVID-19 Combo Kit verification studies revealed no verification of preanalytical specimen stability studies to verify the stability claims

	per the laboratory protocol. No documentation of the specimen storage and preservation; specimen transportation; and acceptability were available for review. Cross refer to D5421-B 3. An interview with the technical supervisor #2 on 9/1/21 at 10:00 am in the office confirmed the above findings. II. Based on the review of the laboratory's policies, the laboratory's records from 2021, and confirmed in an interview revealed the laboratory failed to establish the specimen storage and preservation; specimen transportation; and acceptability criteria for one of one non-EUA approved test (FluV19 RT-PCR (RUO) multiplex kit) for SARS-CoV-2. The findings were: 1. Review of the instructions for use for FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221. Revision 210329.v1) revealed under Specimen Collection, Transport, and Storage Requirements "Sample collection and handling shall be performed per lab procedure, 'specimen collection, handling, transport, and submission'." 2. Review of the laboratory's validation report for FluV19 RT-PCR (RUO) multiplex kit revealed under Specimen Collection, Transport, and Storage Requirements "..., store specimens at 2-8C and ship overnight to the laboratory on ice pack. If a specimen is frozen at -70C or lower, ship overnight to the laboratory on dry ice." 3. Review of the laboratory establishment studies for the FluV19 RT-PCR (RUO) multiplex kit revealed no establishment of the preanalytical specimen stability. No documentation of the specimen storage and preservation; specimen transportation; and acceptability were available for review. Cross refer to D5423 4. An interview with the technical supervisor #2 on 9/1/21 at 10:00 am in the office confirmed the above findings. She stated that she used the package insert for the VTM (viral transport media) as the stability but acknowledged that no establishment studies were performed. Key: EUA=Emergency Use Authrozation RUO - Research use only
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's client service manuals, the laboratory's records, patient test records from May to August 2021, collection kit package insert, and confirmed in an interview, the laboratory failed to document a client service manual for two of three tests (TaqPath COVID-19 Combo Kit and FluV19 RT-PCR (RUO) multiplex kit) to the labortory's clients. The findings were: 1. Review of the laboratory's records from 2021 revealed the laboratory utilized Beaver Collection Kit (Manufacturing License(s): SSSYJXSCB 20161010) as the VTM (viral transport media) for both Covid testing performed. TaqPath COVID-19 Combo Kit (Publication#: MAN0019181, Revision: J.0) FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221. Revision 210329.v1) 2. Review of the laboratory records available revealed no documentation of a client service manual to include the conditions for specimen transporation, specimen processing, and specimen acceptability and rejection for the above tests. (Refer to 5311-I, II). 3. Random review of patient requisitions and corresponding test records from May to August 2021 revealed the laboratory received nasophayngeal swabs collected in Beaver VTM from outside facilities for 12 of 12 patient records reviewed. TaqPath COVID-19 Combo Kit 5/13/21 Patient ID: 0002712 5/13/21 Patient ID: 0003103 5/13/21 Patient ID: 0003104 6/28/21 Patient ID: 0001454 6/28/21 Patient ID: 0003168 6/28/21 Patient ID: 0003564 FluV19 RT-PCR (RUO) multiplex kit 7/28/21 Patient ID: 0001729 7/28

	/21 Patient ID: 0003193 7/28/21 Patient ID: 0004468 8/23/21 Patient ID: 0006509 8 /23/21 Patient ID: 0006512 8/23/21 Patient ID: 0006554 6. An interview with the technical supervisor #2 on 9/1/21 at 10:00 am in the office confirmed the above findings. She confirmed nothing was provided to their clients. Key:VTM=Viral transport media
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 the review of the manufacturer's instructions, laboratory policies, TaqPath COVID-19 Combo Kit validation records, and confirmed in an interview revealed the laboratory failed to document complete verification studies for 1 of 1 EUA approved test (TaqPath COVID-19 Combo Kit) for 2 of 2 instruments (Applied Biosystems QuantStudio 12K Flex Real-Time PCR system (SN#285882151) and 7500 Fast Real-Time PCR system (SN# 275015205)). A. accuracy and precision studies B. preanalytical studies The findings were: A. accuracy study 1. Review of the laboratory's Method Validation policy (Reference# 1650-24) revealed under III. Procedure: Accuracy, "3. Sample must agree with known value within manufacturer stated limits or within 5 to 10% if patient sample used. Constituents with extremely low numerical values must agree within 10 to 15%." 2. Review of the laboratory verification studies for the TaqPath COVID-19 Combo Kit revealed the raw data of accuracy and precision. No documentation of the assessment of accuracy nor precision were available for review for 2 of 2 instruments (Applied Biosystems QuantStudio 12K Flex Real-Time PCR system (SN#285882151) and 7500 Fast Real-Time PCR system (SN# 275015205)). B. preanalytical study 3. Review of the instructions for use TaqPath (Trademark) COVID-19 RNase P Combo Kit (Number MAN0024969 Revision B.0 25 August 2021) under samples and controls revealed "store patient samples according to CDC guidelines." 4. Review of the Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) under Storing and Shipping Respiratory Specimens revealed "Store respiratory specimens at 2-8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below." 5. Review of the laboratory's policy TaqPath COVID-19 Combo Kit approved by the laboratory director on February 1, 2021 under Samples and Controls revealed "Specimens can be stored at 4C for up to 72 hours after collection." 6. Review of TaqPath COVID-19 Combo Kit verification studies revealed no verification of the preanalytical specimen stability to verify the stability claims per the laboratory protocol for 2 of 2 instruments (Applied Biosystems QuantStudio 12K Flex Real-Time PCR system (SN#285882151) and 7500 Fast Real-Time PCR system (SN# 275015205)). 7. An interview with the technical supervisor #2 on 9/2/21 at 1:00 pm in the office confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's policy, laboratory establishment studies, and confirmed in an interview revealed the laboratory failed to document complete establishment studies for 1 of 1 non-EUA approved test (FluV19 RT-PCR (RUO) multiplex kit). A. Accuracy B. Interfering Substances C. Pre-analytical studies The findings were: 1. Review of FluV19 RT-PCR (RUO) multiplex kit package insert (Reference: G210221; Revision:210329 v1) revealed under Intended Use "This kit is a laboratory developed test (LDT)...". A. Accuracy 2. Review of the laboratory's Method Validation policy (Reference# 1650-24) revealed under III. Procedure: Accuracy, "3. Sample must agree with known value within manufacturer stated limits or within 5 to 10% if patient sample used. Constituents with extremely low numerical values must agree within 10 to 15%." 3. Review of the accuracy study for FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221; Revision: 210329.v1) revealed the cq values of the runs did not agree with expected cq values within 10-15% for two of three samples reviewed. Sample: SC2 Mid Titer Target: SARS2 Expected Values (cq): 29.87 10% range: 26.88-32.86 15% range: 25.39-34.35 Three of eight cq values of the run out of the limits: 35.58, 34.45, and 35.23 Sample: SC2 Low Titer Target: SARS Expected Values (cq): 27.82 10% range: 25.04-30.60 15% range: 23.64-32.00 Eight of eight cq values of the run: 32.67, 33.13, 33.24, 32.28, 33.07, 33.39, 33.24, and 33.39 B. Interfering Substances 3. Review of the laboratory's policy revealed no policy established for interfering substances for FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221; Revision: 210329.v1). 4. Review of laboratory establishment studies for FluV19 RT-PCR (RUO) multiplex kit revealed no documentation of the interfering substances study. C. Pre-analytical 5. Review of the laboratory's policy available revealed no policy to establish the pre-analytical criteria for FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221; Revision: 210329.v1). 6. Review of the laboratory's validation report for FluV19 RT-PCR (RUO) multiplex kit revealed under Specimen Collection, Transport, and Storage Requirements "..., store specimens at 2-8C and ship overnight to the laboratory on ice pack. If a specimen is frozen at -70C or lower, ship overnight to the laboratory on dry ice." 7. Review of the laboratory establishment studies for the FluV19 RT-PCR (RUO) multiplex kit revealed no establishment of the preanalytical specimen stability. 8. An interview with the technical supervisor #2 on 9/2/21 at 2:30 pm in the office confirmed the above findings. Key: RUO= Research use only cq= Quantitation Cycle
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3)

	The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: I. Based on the review of the manufacturer's instructions, laboratory's records from July 2021 to August 2021, and confirmed in an interview revealed the laboratory failed to establish and document performance specifications for their QC materials for one of one LDT on the Applied Biosystems QuantStudio 12K Flex Real-Time PCR system and 7500 Fast Real-Time PCR system: FluV19 RT-PCR (RUO) multiplex kit. The findings were: 1. Review of FluV19 RT-PCR (RUO) multiplex kit package insert (Reference: G210221; Revision:210329 v1) revealed under Intended Use "This kit is a laboratory developed test (LDT)...". 2. Review of the laboratory's records from July-August 2021 revealed the laboratory used the following reagents: GRD Control FluV19 PCR Kit Ref: G210221 Lot#: 210429-C Exp: 2022/04 3, Review of the laboratory establishment records available for FluV19 Multiplex kit revealed no documentation of the performance specification for the above control. 4. An interview with the technical supervisor#2 on 9/2/21 at 1:40 pm in the office confirmed the started date of FluV19 multiplex kit was 7/27/21. 5. Random review of patient test records revealed four patients tests were performed using FluV19 multiplex kit. 7/29 /21 MRN#: 0001729 7/29/29 MRN#: 0003193 7/29/21 MRN#: 0004468 8/24/21 MRN#: 0006509 8/24/21 MRN#: 0006512 8/24/21 MRN#: 0006554 6. An interview with the technical supervisor #2 on 9/2/21 at 1:40 pm in the office confirmed the above findings. Key: QC=Quality Control LDT=Laboratory Developed Test RUO=Research Use Only II. Based on the review of laboratory records, extraction worksheets and patient test records from 2021, and confirmed in an interview revealed the laboratory failed to include a mechanism to detect cross-contamination of patient specimens or a blank control for two of two Covid tests on the Applied Biosystems QuantStudio 12K Flex Real-Time PCR system and 7500 Fast Real-Time PCR system. The findings were: 1. Review of the laboratory's records from 2021 revealed the laboratory performed Covid testing using the following two test kits: TaqPath COVID-19 Combo Kit (Publication#: MAN0019181, Revision: J.0) FluV19 RT-PCR (RUO) multiplex kit (Reference: G210221. Revision 210329.v1) 2. Review of the test records from 2021 revealed the laboratory performed the above testing on both the Applied Biosystems QuantStudio 12K Flex Real-Time PCR system (SN#285882151) and 7500 Fast Real-Time PCR system (SN# 275015205). 3. Random review of the labortory's extraction worksheets from May 2021 to August 2021 revelaed no documentation of a blank control or a mechanism to detect cross-contamination of patient specimens for four of four days reviewed. 5/13/21 6/28/21 7/28/21 8/23/21 4. Random review of patient runs for each day reviewed above included the following 12 patients. 5/13/21 Patient ID: 0002712 5/13/21 Patient ID: 0003103 5/13/21 Patient ID: 0003104 6/28/21 Patient ID: 0001454 6/28/21 Patient ID: 0003168 6/28/21 Patient ID: 0003564 7/28/21 Patient ID: 0001729 7/28/21 Patient ID: 0003193 7/28 /21 Patient ID: 0004468 8/23/21 Patient ID: 0006509 8/23/21 Patient ID: 0006512 8 /23/21 Patient ID: 0006554 5. An interview with the technical supervisor #2 on 9/2/21 at 1:40 pm in the office confirmed the above findings. She was unaware she needed to include an NTC for each run. Key: NTC=Non templet Control PC=Positive Control NC=Negative Control
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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, random review of quality control records from 03/2021 to 04/2021, and confirmed in interview, the laboratory failed to establish control procedures that could identify shifts and trends for two of six (DAU1 and DAU2) external quality control toxicology testing on the Shimadzu 8040 LC-MS /MS analyzer. Findings included: 1. Review of the laboratory records from 03/2021 to 04/2021 revealed the laboratory used the following six quality controls: WQCS-Blank: negative control certified drug free urine WQCS-1-Low: in-house prepared quality control WQCS-2-Mid: in-house prepared quality control WQCS-3-High: in-house prepared quality control Drugs of Abuse (DAU1 and DAU2): positive external controls 2. Review of the laboratory policy General Policies and Procedures (CMP-001, effective 09/20/2017) under Control Procedures revealed "Levey Jennings are to be reviewed monthly for each test by general supervisor. Shifts and trends are to be addressed." 3. Random review of quality control records from 03/2021 and 04/2021 revealed the following trends for the following seven of twenty-five analytes for either the low and/or high external quality controls (DAU1 and DAU2) with no documentation of the laboratory addressing the shifts and trends per their lab policy. DAU1 (Low) Benzoylecgonine - range 136-204 3/01/21: 201 3/04/21: 203 3/09/21: 197 3/15/21: 190 3/19/21: 198 3/25/21: 195 3/26/21: 197 3/31/21: 199 DAU2 (High) Benzoylecgonine - range 353-529 3/01/21: 417 3/04/21: 431 3/09/21: 383 3/15/21: 410 3/19/21: 405 3/25/21: 397 3/26/21: 387 3/31/21: 418 DAU1 (Low) Carisoprodol - range 293-439 3/01/21: 421 3/04/21: 436 3/09/21: 420 3/15/21: 426 3/19/21: 427 3/25 /21: 418 3/26/21: 399 3/31/21: 409 DAU2 (High) Carisoprodol - range 3062-4594 3 /01/21: 4297 3/04/21: 4430 3/09/21: 4516 3/15/21: 4178 3/19/21: 4524 3/25/21: 4351 3/26/21: 4081 3/31/21: 4144 DAU2 (High) Clomipramine- range 3204-4806 3/19/21: 4568 3/25/21: 4665 3/26/21: 4511 3/31/21: 4615 DAU2 (High) Codeine - range 3032 - 4548 3/01/21: 3169 3/04/21: 3061 3/09/21: 3211 3/15/21: 3281 3/19/21: 3260 3/25 /21: 3233 3/26/21: 3177 3/31/21: 3177 DAU1 (Low) Cyclobenzaprine - range 262-392 3/01/21: 373 3/04/21: 381 3/09/21: 360 3/15/21: 363 3/19/21: 351 3/25/21: 377 3 /26/21: 381 3/31/21: 380 DAU2 (High) Desipramine - range 2938 - 4406 3/01/21: 4377 3/04/21: 4073 3/09/21: 4310 3/15/21: 4091 3/19/21: 4211 3/25/21: 4048 3/26 /21: 4343 3/31/21: 4330 DAU1 (Low) Mitragynine - Range 63-94 3/01/21: 92 3/04 /21: 93 3/09/21: 93 3/15/21: 89 3/19/21: 90 3/25/21: 93 3/26/21: 89 3/31/21: 90 DAU1 (Low) Benzoylecgonine - range 136-204 4/06/21: 200 4/09/21: 202 4/14/21: 197 4/16/21: 199 4/21/21: 195 4/23/21: 197 4/27/21: 201 4/29/21: 201 DAU2 (High) Benzoylecgonine - range 353-529 4/06/21: 423 4/09/21: 399 4/14/21: 386 4/21/21: 378 4/23/21: 368 4/27/21: 384 4/29/21: 389 DAU1 (Low) Carisoprodol - range 293-439 4/06/21: 425 4/09/21: 428 4/14/21: 432 4/16/21: 431 4/21/21: 395 4/23/21: 422 4 /27/21: 429 4/29/21: 426 DAU2 (High) Cyclobenzaprine - range 2791-4187 4/06/21: 3892 4/09/21: 3912 4/14/21: 3983 4/16/21: 4038 4/21/21: 4048 4/23/21: 3889 4/27 /21: 3890 4/29/21: 3825 DAU1 (Low) Cyclobenzaprine - range 262-392 4/06/21: 350

	4/09/21: 370 4/14/21: 389 4/16/21: 375 4/21/21: 378 4/23/21: 389 4/27/21: 372 4/29 /21: 383 4. Review of the laboratory CMS-116 signed by the laboratory director on 8 /30/21 revealed the laboratory performed 209,044 toxicology tests annually. 5. An interview with the compliance specialist on 9/2/21 at 1300 hours in the office confirmed the above findings.
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 corrective actions and laboratory patient records from 03/2021 and 07/2021, and confirmed in interview, the laboratory failed to evaluate all patient test results obtained in the unacceptable test run and since the last acceptable test run when quality control failed to meet the acceptable range for three of fifteen days reviewed with the toxicology screening testing on the Synermed IR500. Findings included: 1. Random review of quality control corrective actions from 03/2021 and 07/2021 revealed the following three days with corrective actions for the following analytes: BUP and THC (Buprenorphine and Tetrahydrocannabinol). 7/23/21 BUP level 1 2006004K2 repeated, recal 3/05/21 BUP level 1 2006004K2 recal 3/30/21 THC level 2 2008082 recal 2. Review of the laboratory records revealed no documentation of the patient corrective action since the last good QC. A sampling of the patients tested since the last good QC include: 3/29/21 Patient ID A00267 Patient ID A00160 Patient ID A00372 3/04/21 Patient ID A00195 Patient ID A00242 Patient ID A00245 7/21/21 Patient ID A00780 Patient ID A00377 Patient ID A00781 3. An interview with the compliance specialist on 9/2/21 at 1020 hours in the office confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on direct observations, laboratory policies, quality control records, manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory services. (refer to D6086)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observations, review of the laboratory establishment studies, laboratory quality control records and patient logs, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete establishment studies for the non EUA approved Covid PCR testing. Refer to D5423, D5311-II
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, CMS-209 form, Testing Personnel (TP) Competency Assessments from 2020 and 2021, and confirmed in interview, the Technical Supervisor (TS) failed to document one of six of the Competency Assessment components for one of two testing personnel (TP#2). The findings include: 1. Review of the laboratory policy Competency Assessment Policy (#1650-5, effective 1/4/21) revealed "the following six (6) procedures are the minimal regulatory requirements for assessment of competency for all staff performing laboratory testing... direct observation of performance of instrument maintenance and function checks." 2. Review of the CMS-209 form listed TP#2 for Covid PCR high complexity testing. 3. Review of competency assessments for the TP#2 in 2021 did not include one of six components: direct observation of performance of intrument maintenance and function checks. 4. An interview with the technical supervisor #2 on 9/1/21 at 1030 hours in the office confirmed the above findings.