

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2183307	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Interventional Partners, PLLC	Street Address, City, State 2525 W Bellfort Avenue, 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	<p>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. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) attestation statement and proficiency testing records for 2021, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing six of six attestation statements in 2021. Findings include: 1. A review of CAP's Attestation form revealed the following: "As stated in the February 28, 1992 United States Federal Register under Subpart H 493-801 (b)(1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee</p>

and the testing person must sign on the result form." 2. A review of the laboratory's CAP records from 2021 revealed the laboratory failed to have documentation of the laboratory director signing the following 6 attestation statements: - 2021 Molecular Vaginal Panel- second event - 2021 Group B Strep- second event - 2021 Vancomycin-resistant Enterococcus- second event - 2021 Herpes Simplex virus, Varicella Zoster Molecular- second event - 2021 Carbapenem-resistant Organisms- second event - 2021 Methicillin-Resistant Staphylococcus aureus- second event 3. Further review of the attestation statements from the above listed testing events revealed the attestation statements were signed by technical supervisor #3 (as indicated on the CMS 209 form). 4. A review of the laboratory's records revealed the laboratory failed to have documentation of the laboratory director delegating the responsibility of signing proficiency testing attestation statements to technical supervisor #3. 5. An interview with the general supervisor on 12/14/21 at 11:30 a.m. in the break room, after review of the records, confirmed the above findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's accuracy assessment records from 2020 and staff interview, it was revealed that the laboratory failed to have documentation of performing two of two twice annual accuracy assessments for Histology grossing in 2020. Findings include: 1. A review of the laboratory's accuracy assessment records revealed the laboratory failed to have documentation of verifying the accuracy of the Histology grossing at least twice annually in 2020. 2. An interview with the general supervisor (as indicated on the CMS 209 form) on 12/14/21 at 12:35 p.m. in the break room, after review of the records, confirmed the above 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 a random review of patient's test reports from August 2020 to November 2021, and staff interview, it was revealed that the laboratory failed to include the correct suite number of the testing facility on three of eight patient's test reports reviewed from August 2020 and December 2021. Findings include: 1. A random review of patient's test reports from August 2020 to December 2021 revealed the laboratory failed to include the correct suite number of the testing facility on the following 3 patient's test reports: Patient ID: ADGS20-00100 Reported: 8/23/20

Patient ID: ADGS20-00279 Reported: 9/18/20 Patient ID: ADGS21-78808 Reported: 12/6/21 *All of the above listed patient reports indicated the testing was performed in Suite 194. However, the testing (Histology grossing) was performed in Suite 160. 2. An interview with the general supervisor (as indicated on the CMS 209 form) on 12/14/21 at 2:00 p.m. in the break room, after review of the records, confirmed the above findings.

D6127

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing two competency assessments within the first year for five of twelve testing personnel for high complexity testing. Findings include: 1. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical supervisor performing two competency assessments within the first year for the following 5 testing personnel: a) Testing person #3 - Hire date: 10/19/20 - Competency assessment done: 4/16/21 - No documentation of a second competency assessment prior to October 2021 b) Testing person #8 - Hire date: 8/24/20 - Competency assessment done: 2/26/21 - No documentation of a second competency assessment prior to August 2021 c) Testing person #10 - Hire date: 7/13/20 - Competency assessment done: 1/11/21 - No documentation of a second competency assessment prior to July 2021 d) Testing person #6 - Hire date: 9/28/20 - Competency assessment done: 5/3/21 - No documentation of a second competency assessment prior to September 2021 e) Testing person #7 - Hire date: 8/27/20 - Competency assessment done: 3/19/21 - No documentation of a second competency assessment prior to August 2021 2. An interview with the general supervisor (as indicated on the CMS 209 form) on 12/14/21 at 10:50 a.m. in the break room, after review of the records, confirmed the above findings.