

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659755	(X3) Date Survey Completed 12/17/2021
Name of Provider or Supplier Preferred Hospital Leasing Hemphill Inc	Street Address, City, State 2301 Worth Street, Hemphill, 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	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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5455	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g)</p> <p>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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: A Based on review of the laboratory's establishment studies and quality control (QC) records for the BioFire Respiratory Panel 2.1 (RP2.1) for February to November of 2021, review of Instructions for Use and laboratory's policies for the same panel, review laboratory's Individualized Quality Control Plan (IQCP) establishment studies for the RP2.1 panel, review of laboratory's COVID test summary and staff interview it</p>

was determined the laboratory failed to document performance of QC at least once each day of testing for 170 of 179 days testing was performed. Findings included: 1. Review of the laboratory's BioFire Respiratory Panel 2.1 (RP2.1) establishment studies revealed the panel was implemented in January of 2021. 2. Review of the laboratory's 2021 QC records for the BioFire Respiratory Panel 2.1 (RP2.1) revealed QC was performed only 9 of 179 testing days as follows: 02/20/2021 03/02/2021 04/12/2021 05/03/2021 07/26/2021 08/03/2021 08/20/2021 08/23/2021 09/14/2021 3. Review of the laboratory's Instructions for Use (REF 423742) for the BioFire Respiratory Panel 2.1 (RP2.1) under section for External Controls (page 15) and laboratory's policies revealed: a. "External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable." b. The laboratory did not have a policy specifying frequency of external controls for BioFire Respiratory Panel 2.1 (RP2.1) QC. 4. Review laboratory's Individualized Quality Control Plan (IQCP) establishment studies for the RP2.1 panel revealed the studies were incomplete (refer to D5455B) 5. Review of the laboratory's COVID test summary revealed there were 390 tests performed using the BioFire Respiratory Panel 2.1 (RP2.1) from February to November of 2021 (refer to master list attached for patient sample information). 6. In an interview on 12/17/2021 at 1640 hours in the conference room the General Supervisor (as described in the CMS Form 209 signed by laboratory director on 12/16/2021) stated that he thought the the IQCP for the RP2.1 panel was completed, therefore QC was not needed on the days of patient testing. This confirmed the findings. B. Based on interview with laboratory's General Supervisor, review of the laboratory's Individualized Quality Control Plan (IQCP) establishment studies for BioFire Respiratory Panel 2.1 (RP2.1) and lack of documentation, it was determined the laboratory failed to include complete Risk Assessment (RA), Quality Control Plan (QCP) and Quality Assessment (QA) as part of the Individualized Quality Control Plan (IQCP) for this panel. Findings included: 1. In an interview on 12/17/2021 at 1640 hours in the conference room the laboratory's General Supervisor (GS) indicated that the laboratory was seeking to establish IQCP for the BioFire Respiratory Panel 2.1 (RP2.1) in which Quality Control (QC) frequency would be reduced to once each lot number or every 30 days. 2. Review of the IQCP establishment studies for the BioFire Respiratory Panel 2.1 (RP2.1) revealed there was no risk assessment evaluation by the laboratory for either of the pre-analytic, analytic, post-analytic test phases, environmental factors or personnel factors that may affect test performance. 3. Further review of the IQCP establishment studies for the BioFire Respiratory Panel 2.1 (RP2.1) revealed the laboratory performed only 10 days of QC during IQCP establishment studies. There was no QCP establishing the new frequency of QC for said panel. 4. In addition, review of the IQCP establishment studies for the BioFire Respiratory Panel 2.1 (RP2.1) revealed no Quality Assessment component of the IQCP for the panel. 5. In an interview at 12/17/2021 at 16:55 hours in the conference room the GS 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 quality control (QC) records for January to

	<p>December of 2021, review of the Individualized Quality Control Plan (IQCP) establishment studies, review of CMS Form 116 and staff interview it was determined the laboratory's Quality Assessment failed to ensure QC was established and maintained for the BioFire Respiratory Panel 2.1 (refer to D5455).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for January to December of 2021, review of the Individualized Quality Control Plan (IQCP) establishment studies, review of CMS Form 116 and staff interview it was determined the Laboratory Director failed to ensure QC was established and maintained for the BioFire Respiratory Panel 2.1 (refer to D5455).</p>
<p>D6117</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for January to December of 2021, review of the Individualized Quality Control Plan (IQCP) establishment studies, review of CMS Form 116 and staff interview it was determined the Technical Supervisor failed to ensure QC was established and maintained for the BioFire Respiratory Panel 2.1 (refer to D5455).</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of personnel competency assessments for 2020 and 2021 and staff interview it was determined the laboratory's Technical Supervisor failed to document competency evaluation at least twice during the first year for 1 of 7 testing persons. Findings included: 1. Review of personnel records revealed Testing Person number 3 (as described on CMS Form 209 signed by the laboratory director on 12/16/2021) was hired on 6/12/2020. 2. Review of the personnel competency assessments for 2020 and 2021 revealed Testing Person's</p>

number 3 (TP3) had competency evaluations documented as follows: Competency assessment started on 06/11/2021; completed on 09/02/2021 3. In an interview on 12/17/2021 at 1030 hours in the conference room the General Supervisor (as described on CMS Form 209 signed by the laboratory director on 12/16/2021) confirmed that there was only 1 competency evaluation documented for TP3 in the first year of employment.