Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660081	09/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Houston Health Department Bureau Of Laboratory	2250 Holcombe Blvd, 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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 803 Condition: Laboratories Successful Participation
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records from the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing program for 2017 and 2018 it was determined the laboratory failed to successfully participate in a proficiency testing program in the specialty of Bacteriology. (D2028)

D2028	BACTERIOLOGY CFR(s): 493.823(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Review of WSLH proficiency testing records for 2017 and 2018 and interview facility personnel found that the laboratory failed to attain satisfactory performance in two of three consecutive proficiency testing events for Bacteriology. The laboratory received unsatisfactory scores (less than 80%) in the second testing event of 2017 (63%) and the first testing event of 2018 (0%). Findings included: 1. Review of WS LH proficiency testing records found : a. The laboratory submitted unacceptable responses for five of five specimens in the 2017 second testing event for bacteriology. No results were entered for Plesiomonas, Shigella, or Yersinia for any of the specimens tested (NP-6, NP-7 NP-8, NP-9 and NP-10) b. The laboratory failed to submit results to the proficiency testing agency in the 2018 first testing event resulting in a score of 0%. Interview of the QA/officer conducted on September 7, 2018 at 9:49 AM confirmed the above findings.
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: Based on review of the laboratory's submitted Form CMS-209, review of laboratory policy, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of a competency assessment for 12 of 19 technical supervisors and 12 of 19 general supervisors. Findings were: 1. Review of the laboratory policy Competency Assessment of Laboratory Staff (06/28/18) revealed "competency assessment will be performed for each clinical consultant, technical consultant, technical supervisor, and general supervisor at least annually based on their regulatory responsibilities." 2. Review of the laboratory CMS-209 revealed 19 technical supervisors and 19 general supervisors. 3. Review of the laboratory records from 2016 and 2017 revealed no documentation of a competency assessment for 12 of 19 technical supervisors and 12 of 19 general supervisors (TS /GS). TS/GS#3 (hire date 05/27/14) TS/GS#6 (hire date 9/9/14) TS/GS#7 (hire date 1 /9/16) TS/GS#8 (hire date 11/26/12) TS/GS#9 (hire date 03/20/12) TS/GS#12 (hire date 10/2017) TS/GS#13 (hire date 04/13/1993) TS/GS#14 (hire date 08/28/06) TS /GS#16 (hire date 12/4/06) TS/GS#17 (hire date 04/01/13) TS/GS#18 (hire date 09/08 /08) TS/GS#19 (hire date 07/13/15) 4. An interview with the laboratory manager on 09 /04/18 at 1440 hours in the conference room confirmed the above findings. He was unaware the lead techs who were responsible for performing competencies required a competency as a technical supervisor and general supervisor. Key: CMS - Center of Medicare and Medicaid Services
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 records, manufacturer's instructions, quality control records, patient records, and confirmed in interview, the laboratory failed to perform a negative and positive control for each virus type and subtype on each day of patient testing for the GenMark Dx eSensor Respiratory Viral Panel on the eSensor XT-8 PCR instrument. Findings were: 1. Review of the GenMark Dx eSensor Respiratory Viral Panel revealed the laboratory tested for the following virus type and subtypes on the eSensor XT-8 PCR instrument. Influenza A Influenza A H1 Influenza A H3 Influenza A 2009 H1N1 Influenza B Respiratory Syncytial Virus Subtype A Respiratory syncytial virus subtype B Parainfluenza Virus 1 Parainfluenza Virus 2 Parainfluenza Virus 3 HumanMetapneumovirus Human Rhinovirus Adenovirus species B/E Adenovirus species C 2. Review of the GenMark Dx eSensor Respiratory Viral Panel Package insert (PI1032 Rev G) revealed "good laboratory practice recommends the use of positive and negative controls to assure functionality of reagents and proper performance of the assay procedure. Positive and negative controls are intended to monitor for substantial reagent failure...a negative control should be included with each run...viral target positive controls should be included with each batch of patient specimens." 3. Review of the GenMark Dx eSensor Respiratory Viral Panel laboratory records revealed the laboratory performed an external positive quality control testing for 5 of the 14 virus type and subtypes analyzed on the eSensor XT-8 PCR instrument. The laboratory used previously positive specimens for the positive external controls. Influenza A Influenza A H3 Influenza B Respiratory syncytial virus subtype B Parainfluenza Virus 3 4. Random review of patient records from January to March 2017 revealed 9 of 20 patients that were tested with only the above positive controls for each run. 1/31/17 Sample ID: 4008033 Result: Adenovirus Species C detected 2/9/17 Sample ID: 4010482 Result: Respiratory Syncytial Virus A detected 2/14/17 Sample ID: 4012223 Result: Human Metapneumovirus detected 2/14/17 Sample ID: 4012225 Result: Human Rhinovirus detected 3/25/17 Sample ID: 4024046 Result: Human Rhinovirus detected 3/27/17 Sample ID: 4024311 Result: Influenza B detected; B/Victoria lineage detected 3/28 /17 Sample ID: 4024328 Result: Influenza 2009 A(H1N1) pdm virus detected 3/7/17 Sample ID: 4018271 Result: Adenovirus Species B/E detected 3/9/17 Sample ID: 4018675 Result: Human Metapneumovirus detected 5. An interview with the general supervisor # 6 on 9/6/18 at 1525 hours in the conference room confirmed the above findings. She was unaware the laboratory was required to perform an external positive control for each virus type and subtype.
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 review of the manufacturer's instructions, laboratory records, quality control (QC) records, and confirmed in interview, the laboratory failed to establish the QC ranges for the Bioplex 2200 immunology analyzer for HIV Ag-Ab testing. Findings were: 1. Review of the laboratory records revealed the laboratory performed HIV Ag-Ab assay for the following analytes on the Bioplex 2200 immunology analyzer. HIV-1 Ag HIV-1 M Ab HIV-1O Ab HIV-2 Ab 2. Review of the Bioplex 2200 System Operation Manual (LB001241revA) revealed "upon receipt of a new kit lot and/or control lot, qualification of the new combination is required by verifying performance against the published acceptable QC range." 3. Review of the 2018 QC records from the Bioplex 2200 immunology analyzer revealed the laboratory used the following control lot number with reagent pack lot # 300835, exp 2/28/19 with no documentation of the laboratory establishing the target mean values and standard deviations. BioPlex 2200 HIV Ag-AB Control Set Lot 50428, exp 6/20/19 (in use 8/1 /18) Negative Control (50429) HIV-1 Ag (acceptable range: 0 to .24) HIV-1 M Ab (acceptable range: 0 to 0.2) HIV-1O Ab (acceptable range: 0 to 0.22) HIV-2 Ab (acceptable range: 0 to 0.21) Positive Control (50430) HIV-1 Ag (acceptable range: 4.10 - 6.16) Positive Control (50431) HIV-1 M Ab (acceptable range: 3.70 - 5.54) HIV-1O Ab (acceptable range: 3.58 - 5.38) HIV-2 Ab (acceptable range: 2.70 - 4.04) 4. Random review of patient records from August 2018 revealed the laboratory performed HIV Ag-Ab patient testing with the above quality control. 8/2/18 Sample ID 4175232 Result: Non-Reactive for HIV 8/06/18 Sample ID 4175838 Result: Non-Reactive for HIV 8/6/18 Sample ID 4175719 Result: Non-Reactive for HIV 8/24/18 Sample ID 4182940 Result: Non-Reactive for HIV 8/29/18 Sample ID 4184015 Result: Non-Reactive for HIV 8/30/18 Sample ID 4184477 Result: Non-Reactive for HIV 4. An interview with the general supervisor #2 on 9/5/18 at 1530 hours in the conference room confirmed the above findings. She was unaware she needed to establish the QC ranges.
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 the laboratory quality control records, laboratory corrective

	actions, and confirmed in interview, the laboratory failed to document corrective actions when quality control was outside of acceptable range for the HIV Ag-Ab testing on the Bioplex 2200 immunology analyzer. Findings were: 1. Review of the August 2018 quality control records revealed 2 of 20 days when the quality control was outside of the acceptable range for the following analyte with no documentation of the corrective action. Control lot 50428, exp 6/20/19 Positive control (50431) HIV-2 Ab 8/7/18 Result: 2.59 (acceptable result 2.70 - 4.04) 8/9/18 Result 2.67 (acceptable result 2.70 - 4.04) 2. Review of the August 2018 patient log revealed the laboratory performed HIV Ag-Ab patient testing on the above dates. Patient ID: 4175838, 4175719, 4175232 3. An interview with the general supervisor #2 on 9/5/18 at 1530 hours in the conference room confirmed the above findings. She acknowledged that the laboratory personnel should document the corrective action.
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 laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory quality assessment policies failed to identify, monitor, and correct problems in the analytic systems as evidenced by: 1. The laboratory failed to perform a negative and positive control for each virus type and subtype on each day of patient testing for the GenMark Dx eSensor Respiratory Viral Panel on the eSensor XT-8 PCR instrument. Refer to D5449 2. The laboratory failed to establish the QC ranges for the Bioplex 2200 immunology analyzer for HIV Ag-Ab testing. Refer to D5469 3. The laboratory failed to document corrective actions when quality control was outside of acceptable range for the HIV Ag-Ab testing on the Bioplex 2200 immunology analyzer. Refer to D5783