Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1050724	09/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cypress Ob Gyn	10680 Jones Rd Ste 600, 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	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 certification 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 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.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on review of the laboratory's submitted test volumes and Form 116, review of laboratory's policies and procedures, review of SARS-CoV-2 results' reporting records and staff interview, it was determined the laboratory failed to report negative ("not

	detected") SARS-CoV-2 PCR (polymerase chain reaction) results as required by 42CFR 493.41 and 493.1100(a) for 8 of 8 months the laboratory has been in operation, from January to September of 2022. Findings included: 1. Review of the laboratory's submitted test volumes and Form 116 revealed the laboratory performed SARS-CoV-2 testing using the Cepheid Xpress SARS-CoV-2/FLU/RSV PCR testing platform, with an estimated annual volume of 1800 tests. 2. Review of laboratory's SARS-CoV-2/FLU/RSV policy/procedure (placed into effect January 2022) revealed the laboratory's protocols did not address reporting of negative SARS-CoV-2 results as required by 42CFR 493.41 and 493.1100(a). 3. Review of SARS-CoV-2 results' reporting records revealed the laboratory did not report negative SARS-CoV-2 results as required for 8 of 8 months the laboratory has been in operation, from January to September of 2022. 4. In an interview on 09/12/2022 at 1025 in the office, the laboratory's Technical Consultant confirmed the 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 209, review of personnel competency assessment records for 2022, review of laboratory's policies and staff interview, it was determined the laboratory failed to document competency assessment of one of one Technical Consultants employed by the facility. Note: The facility started laboratory operations in January of 2022. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by Laboratory Director on 09/12 /2022) revealed the laboratory employed one Technical Consultant. 2. Review of personnel competency assessment records for 2022 revealed the laboratory did not have documentation of competency assessment for one of one Technical Consultants employed by the facility. 3. Review of laboratory's policies revealed the policies did not include protocols for competency assessment for laboratory's Technical Consultant. 4. In an interview on 09/12/2022 at 1130 hours in the office, the laboratory's Technical Consultant confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's GeneXpert Dx System Operator Manual, review of the laboratory's Individualized Quality Control Plan

	(IQCP) establishment records for the Cepheid Xpert CT/NG and Xpert Xpress CoV-2 /Flu/RSV PCR (polymerase chain reaction) testing panels and staff interview, it was determined the laboratory' failed to complete the IQCP 7-day interval establishment studies for the above panels for 2 of 2 testing instruments. Findings included: 1. Surveyor's observations in the laboratory on 9/12/2022 at 1030 hours revealed the laboratory's used 2 GeneXpert GX-IV instruments (serial number 110010026 and 110010028) connected to one computer. 2. Review of manufacturer's GeneXpert Dx System Operator Manual (document 302-4070, Rev. B December 2020) revealed: "- GeneXpert Dx system refers to the complete system including the computer, GeneXpert instrument and barcode scanner. - GeneXpert instrument refers only to the components used to process the samples." And "- The GeneXpert GX-IV instrument consists of up to four modules. Each module processes one sample. Up to four GeneXpert GX-IV instruments can be connected to one computer." 3. Review of the laboratory's IQCP establishment records for the Cepheid Xpert CT/NG and Xpert Xpress CoV-2/Flu/RSV PCR testing panels revealed the goal was to establish external QC frequency of every 7 days. 4. Further review of the laboratory's IQCP establishment records revealed the IQCP studies failed to document performance of external positive and negative control each day of the 7 day IQCP interval for each instrument as follows: Cepheid Xpert CT/NG panel external controls performed: Date: Instrument: Instrument: ---------- 110010026 110010028 01/14/2022 POS & NEG (---) 01/15/2022 POS NEG 01/16/2022 NEG POS 01/17/2022 POS (---) 01/18 /2022 (---) POS & NEG 01/19/2022 (---) POS & NEG 01/20/2022 POS NEG Cepheid Xpert Xpress CoV-2/Flu/RSV PCR panel external controls performed: Date: Instrument: Instrument: ---------- 110010026 110010028 01/14/2022 POS & NEG POS & NEG 01/15/2022 POS NEG 01/16/2022 (---) POS & NEG 01/17/2022 POS & NEG NEG 01/18/2022 POS & NEG POS & NEG 01/19/2022 (---) POS & NEG 01/20 /2022 POS & NEG (---) Legend: POS=Positive Control NEG=Negative Control (---)= No Controls performed 5. In an interview on 09/12/2022 at 1230 hours in the conference room the laboratory's Technical Consultant stated that since up to 4 instruments comprise a test system and are considered as one, each of the individual instruments did not have to have positive and negative controls performed for each of the seven days in the IQCP interval. This 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 laboratory's policies and procedures, review of the laboratory's Quality Assessment (QA) documents for January to August of 2022 and staff interview, it was determined the laboratory failed to document review of quality assessment for 1 of 8 months reviewed as per laboratory's policy. Findings included: 1. Review of laboratory's policy MICRO-005 (Version 1.0, signed into effect January 2022) revealed: "The QAP (quality assessment plan) is the continuous process of monitoring the effectiveness of the QCP (quality control plan)." AND "PROCEDURE A. Monthly Review of maintenance, quality control and corrective action data ... B. Evaluation of errors relating all phases of the testing process ... C. Periodic review of the testing personnel ... D. Reevaluation and reapproval of the risk assessment, quality

	control plan and quality assessment plan based on any unexpected findings." 2. Review of the laboratory's QA documents for January to August of 2022 revealed no documentation of QA review by the Laboratory Supervisor, Technical Consultant and Laboratory Director (as required by the QA form) for the month of February of 2022, 1 of 8 months reviewed. 3. In an interview on 09/12/2022 at 1425 hours in the office, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted test volumes and Form 116, review of SARS-CoV-2 (COVID) results' reporting records and staff interview, it was determined the Laboratory Director failed to ensure the laboratory followed 42CFR 493.41 and 493.1100(a) requirement for COVID result reporting. Findings included: 1. Review of the laboratory's submitted test volumes and Form 116 revealed the laboratory performed COVID testing. 2. Review of COVID results' reporting records revealed the laboratory did not report COVID results as mandated by 42CFR 493.41 and 493.1100(a) requirement. 3. In an interview on 09/12/2022 at 1025 in the office, the laboratory's Technical Consultant confirmed the findings.
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 surveyor's observations, review of manufacturer's GeneXpert Dx System Operator Manual, review of the laboratory's Individualized Quality Control Plan (IQCP) establishment records and staff interview, it was determined the Laboratory Director failed to ensure the IQCP 7-day interval establishment studies were complete. Refer to D5445.
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 policies and procedures, review of the laboratory's Quality Assessment (QA) documents for January to August of 2022 and staff interview, it was determined the Laboratory Director failed to ensure QA was maintained. Refer to D5791.