Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1050724	04/30/2024
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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2023, and staff interview, the laboratory failed to retain the Cepheid Xpress analyzer printouts for three of three proficiency testing events in 2023. Findings include: 1. A review of the laboratory's API testing records revealed the laboratory participated in the following 3 testing events in 2023: - 2023 Microbiology- 1st Event - 2023 Microbiology- 2nd Event - 2023 Microbiology- 3rd Event 2. Further review of the API testing records revealed the laboratory failed to retain the analyzer printouts for the Cepheid Xpress analyzer for all 3 testing events in 2023. 3. In an interview on 4/30/24 at 2:05 p.m. in the office, the laboratory supervisor revealed the laboratory disposed of the analyzer printouts once they entered the results into API's website. This confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment, at least twice during the first year of testing, for one of two testing personnel performing moderate complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 2 testing personnel performing moderate complexity testing on the Cepheid Xpress and BD Affirm analyzers. 2. A review of the laboratory's personnel records revealed the following testing personnel, their hire date, and date(s) a competency assessment was performed: a) Testing person #2 Hire date: August 2022 Competency assessment performed: August 2022 Based on the hire date, testing person #2 should have had at least 2 competency assessments performed prior to August 2023. 3. In an interview on 4/30/24 at 1:50 p.m. in the office, the laboratory supervisor, after review of the records, confirmed the above findings.