Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383711	01/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Obstetrical & Gynecological Associates Pc	330 Laurel Street, Suite #1100, Des Moines, IA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 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 workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 1: 10 pm on 01/11/2022, the laboratory director failed to attest to the routine integration of PT samples into the patient workload for six out of six proficiency testing events from 01/01/2020 - 12/31/2021. The findings include: 1. For 2020 event 1, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology. 2. For 2020 event 2, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology. 3. For 2020 event 3, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology. 4. For 2021 event 1, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology. 5. For 2021 event 2, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology. 6. For 2021 event 3, the laboratory director did not sign the following PT attestation statements: core chemistry, hematology/coagulation, and microbiology.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
A. Based on review of the TOSOH AIA-360 maintenance records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 01/11/2022, the laboratory failed to document weekly maintenance on the TOSOH AIA-360 instrument for two out of four weeks and monthly maintenance for one out of one month of patient testing from 08/01/2021- 08 /31/2021. The findings include: 1. According to the TOSOH AIA-360 Maintenance Schedule, the manufacturer requires the laboratory to perform and document cleaning of the substrate line with alcohol weekly. 2. The TOSOH AIA-360 Maintenance Schedule indicated that the laboratory did not document weekly maintenance during the following weeks: 08/20/2021 and 08/27/2021. 3. According to the TOSOH AIA-360 Maintenance Schedule, the manufacturer requires the laboratory to perform and document the following monthly maintenance: *Clean sample area with ethanol *Clean diluent and wash reservoirs with 1:10 dilution of Clorox *Rinse reservoirs with Reagent Grade Type I water *Clean B/F Probe 4. At the time of the survey, personnel identifier #3 confirmed that the laboratory failed to document weekly maintenance for the weeks of 08/20/2021 and 08//27/2021 and monthly maintenance for August 2021. B. Based on review of the BD Max maintenance records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 01/11/2022, the laboratory failed to document weekly maintenance on the BD Max instrument for one out of four weeks and monthly maintenance for one out of one month of patient testing from 08/01/2021- 08 /31/2021. The findings include: 1. According to the BD Max maintenance log sheet, the manufacturer requires the laboratory to reboot the instrument and back-up the instrument database weekly. 2. The BD Max maintenance log sheet indicated that the laboratory did not document weekly maintenance during the week of 08/20/2021. 3. According to the BD Max maintenance log sheet, the manufacturer requires the laboratory to monitor for DNA contamination monthly. 4. At the time of the survey, personnel identifier #3 confirmed that the laboratory failed to document weekly maintenance for the week of 08/20/2021 and monthly maintenance for August 2021. C. Based on review of the Sysmex XP-300 maintenance records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 01/11/2022, the laboratory failed to document weekly maintenance on the Sysmex XP-300 instrument for four out of four weeks of patient testing from 08/01/2021- 08/31/2021. The findings include: 1. According to the Sysmex XP-300 Maintenance Log, the manufacturer requires the laboratory to clean the SRV tray weekly. 2. At the time of the survey, personnel identifier #3 confirmed that the laboratory failed to document weekly maintenance on the Sysmex XP-300 from 08/01/2021- 08/31/2021.