Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2167130	09/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Indiana Regional Medical Center	120 Irmc Drive, Suite 150, Indiana, PA	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of laboratory chemicals and interview with the quality manager (QM) and general supervisor (GS), the laboratory failed to label 1 of 2 4L containers of Supelco Omnisolv acetonitrile and 13 of 13 4L containers of Supelco Omnisolv Methanol LCMS Grade chemicals to indicate their expiration dates. Findings include: 1. On the day of survey, 09/15/2021, observation of the laboratory's chemical cabinet revealed, the following chemicals were not labeled to indicate their expiration dates: - 12 of 13 containers of Supelco Omnisolv Methanol Lot - #01183. - 01 of 13 containers of Supelco Omnisolv Methanol Lot - #611201. - 01 of 02 containers of Supelco Omnisolv Acetonitrile - Lot #60220. 2. The QM confirmed findings above on 09/15/2021 around 2:40 pm.
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 observation of the laboratory thermometers, lack of documentation, and interview with the quality manager (QM) and general supervisor (GS), the laboratory failed to perform maintenance/ calibration on 4 of 4 thermometers in use from 2020 to the day of survey. Findings include: 1. On the day of survey, 09/15/2021, observation of the laboratory thermometers revealed 2 of 2 Thermo Scientific thermometer were due for maintenance: - Serial Number (S/N) 181559664 Due 08/30/2020. - S/N 181595239 Due 09/18/2020. 2. The laboratory could not provide maintenance /calibration records for 2 of 2 Acu - Rite thermometers in use. 3. The laboratory could not provide a policy for the maintenance /calibration of thermometers. 4. The QM and GS confirmed the findings above on 09/15/2021 around 2:35 pm. B. A. Based on observation of the laboratory centrifuge and pipettes, review of records and interview with the quality manager (QM) and general supervisor (GS), the laboratory failed to perform annual Maintenance/ calibration on 1 of 1 Elite Diagnostics Centrifuge and on 3 of 3 pipettes in 2020. Finding Include: 1. The Elite Diagnostics Preventive Maintenance document states, "Yearly documentation centrifuge". 2. The Laboratory Pipette Calibration procedure states, "To ensure accuracy, it is necessary to check pipette calibration annually". 3. On the day of survey, 09/15/2021, review of instrument maintenance/ calibration records revealed, the following instruments were not Maintenance/ calibrated annual in 2020: 4. 1 of 1 Elite Diagnostics Centrifuge: S /N 40914440. Calibration performed 11/18/2019 and 01/29/2021. 5. 3 of 3 Pipettes performed 10/14/2019 and 01/29/2021. - Brand Transferpette Multichannel 30-300 micro liters. S/N: 18M80218. - Eppendorf Research Plus Micropipette, 100- 1000 micro liters. S/N: L30138G. - Eppendorf Reserach Plus Micropipette, 10- 100 micro liters. S/N: O27233H. 6. The QM and GS confirmed the findings above on 09/15 /2021 around 1:35 pm.
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 the quality assurance (QA) policy and interview with the quality manager (QM) and general supervisor (GS), the laboratory director (LD) failed to ensure QA programs were maintained to assure the quality of laboratory services provided in 2019 and 2021. Findings Include: 1. The QA policy states, "Review the monitors (s) assigned for each month". 2. On the date of survey, 09/15/2021, review of the QA documents revealed, the LD did not perform or sign the following monthly review logs: - November 2019 - Not signed by LD. May 2021 - Not signed by LD. June 2021 - Not performed or documented. July 2021 - Not performed or documented. August 2021 - Not performed or documented. 3. The QM confirmed the findings above on 09/15/2021 around 02:12 pm.