Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0369440	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mervin G Wolff Md	3011 West Grand Blvd Suite 210, Detroit, MI	

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
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 record review and interview with the Laboratory Director, the laboratory failed to follow written policies to assess laboratory personnel competency for 2 (September 2019 to September 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Laboratory Director Responsibilities" policy revealed a section stating, "Ensure all personnel have appropriate training and demonstrate competency in performing test operations." 2. A review of the laboratory's records revealed a lack of documentation of competency assessments between September 2019 and September 2021. 3. An interview on 9/9/21 at 2:30 pm with the Laboratory Director confirmed the laboratory did not follow its procedure to assess the competency of laboratory personnel.
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 and interview with the Laboratory Director, the laboratory failed to ensure the expiration date, reflecting the change in stability once the quality control material was opened, was labeled on quality control samples for the current set of 3 vials in use. Findings include: 1. A review of the laboratory's "Adherence to Procedures regarding expired Medonic M controls" policy revealed a section stating, "Label opening date on each control. Discard controls after 7 days of opening. No patient testing allowed with expired controls." 2. An observation on 9/9/21 at 11:51 am revealed the quality control materials in the refrigerator were not labeled with the new expiration date reflecting the stability of opened quality control vials according to the laboratory's policy. 3. An interview on 9/9/21 at 2:30 pm with the Laboratory Director confirmed the quality control vials did not have the expiration date on the labels reflecting the new expiration date once opened.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure control materials were not used when they exceeded their expiration date for 1 (12/21/20) of 51 testing dates reviewed. Findings include: 1. A review of the laboratory's "Adherence to Procedures regarding expired Medonic M controls" revealed a section stating, "Verify Lot Numbers and Expiration Dates of controls prior to testing. Discard expired controls." 2. A review of the laboratory's quality control testing records revealed an "EC" flag on the reports indicating the quality control materials were expired for testing on 12/21/20 under the 220082 lot number. 3. A review of the laboratory's quality control inserts revealed the 220082 lot of quality control materials had an expiration date of 12/18/20. 4. An interview on 9/9/21 at 2:30 pm with the Laboratory Director confirmed the laboratory did not ensure quality control materials were not used when the expiration date had been exceeded. ***This is a repeated deficiency from the 8/27/21 recertification survey.***