

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0369440	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Mervin G Wolff Md	Street Address, City, State 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to retain 6 (21705-5, 21708-2, 21712-2, 21803-0, 21806-2, and 21811-3) of 10 manufacturer's package insert reviewed from 9/29/17 to 8/27/19. Findings include: 1. Record review revealed the laboratory was using Boule "CDS Control Diff" control material. 2. Record review of the "Clinical Diagnostic Packing Lists" forwarded to the physicians office when requested and faxed to the surveyor on 8/29/19 revealed 6 of the 10 shipments the laboratory did not have documentation of the manufacturer's package insert as follows: a. 21705-5 b. 21708-2 c. 21712-2 d. 21803-0 e. 21806-2 f. 21811-3 3. During the interview on 8/27/19 at approximately 12:45 p.m., the LD confirmed he has taken the manufacturer's package inserts home and not returned them to the office.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, patient log review, and interview with the Laboratory</p>

Director (LD), the laboratory was using Boule "CDS Control Diff" hematology control material that exceeded the manufacturer's expiration date for 6 (21705-5, 21708-2, 21712-2, 21803-0, 21806-2, and 21811-3) of 10 lots used between 9/27/17 to 8/27/19. Findings include: 1. Record review of the daily quality control printouts at approximately 12:46 p.m. revealed 6 (21705-5, 21708-2, 21712-2, 21803-0, 21806-2, and 21811-3) of 10 quality control lots flagged as "EC = expired controls" on the daily printouts on the following dates: a. 2017 1. 9/29/17 - low control lot #21705-5 2. 10/2/17 - normal and high control lot #21705-5 3. 12/28/17 - normal control lot # 21708-2 b. 2018 1. 5/3/18 - 6/12/18 - low, normal, and high controls lot# 21712-2 2. 8 /6/18-8/7/18 - low, normal, and high controls lot# 21803-0 3. 11/1/18 - 11/2/18 - low, normal, and high controls lot# 21806-2 c. 2019 1. 4/11/19 - 6/21/19 - low control lot# 21811-3 2. Review of the patient testing log showed 70 patients were tested on the above dates. 3. During the interview on 8/27/19 at approximately 1:00 p.m., the LD confirmed the daily quality control printouts revealed the lot numbers had expired.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

. Based on policy review, surveyor review of calibration records, and interview with the Laboratory Director (LD), the laboratory failed to follow and document calibration procedures for 1 (due 05/2019) of 4 semi-annual calibrations reviewed for 2017, 2018 and 2019. Findings include: 1. The "Quality Assurance Policy" states "calibration will be performed every 6 months." 2. Review of the calibration records revealed the laboratory did not have any documentation to show the calibration due 05/2019 was performed. 3. During the interview on August 27, 2019 at 10:47 a.m. the LD confirmed the laboratory had not performed the calibration procedures every six months.