Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0490166	01/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bretshire Medical Clinic	7030 Bretshire, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: An unannounced onsite B-visit was conducted on 01/16/19. The laboratory had moved to their permanent location on 04/2018. Based on surveyor observations, review of laboratory records, and confirmed in interview, the laboratory failed to establish and written policies and procedures for patient collection and processing for the complete blood count (CBC) testing on the Sysmex KX21N hematology analyzer. Findings were: 1. Surveyor observations on 1/16/19 at 1116 hours in the laboratory revealed testing person (TP) #2 performed a CBC on patient JL13320. 2. Further review of the EDTA microtainer tube revealed no unique identifier. 3. An interview with TP#2 on 1/16/19 at 1120 hours revealed that since he "just collected the specimen, he knew who the patient was." He acknowledged that the microtube had no unique identifier on the tube. 4. Review of the laboratory records available revealed no written policy for the CBC patient collection and processing that included criteria for the following: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. 5. An interview with the primary testing person on 1/16/19 at 1230 hours confirmed the above findings.

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: An unannounced onsite B-visit was conducted on 01/16/19. The laboratory had moved to their permanent location on 04/2018. A. Based on review of manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to ensure that in-use Eight Check 3WP-Xtra QC (quality control) material were labeled with the revised expiration dates according to the manufacturer. Findings included: 1. Review of the manufacturer's instructions for the Eight Check 3WP-Xtra manufacturer's instructions (AQ578643B) revealed "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C." 2. A tour of the laboratory on 1/16/19 at 1108 hours in the laboratory revealed the laboratory stored Eight Check 3WP-Xtra quality control for the Sysmex KS-21N hematology analyzer in the refrigerator with no documentation of the revised expiration dates. Lot 83110710 exp 2/13/19 Lot 83110711 exp 2/13/19 Lot 83110712 exp 2/13/19 3. Review of the laboratory billing report from January 2018 to December 2018 revealed the laboratory performed 7356 CBC testing using the Sysmex KX21N hematology analyzer. Refer to patient alias list. 4. An interview with the primary testing person on 1/16/19 at 1130 hours confirmed the above findings. B. Based on review of manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to ensure that in use reagents for the Sysmex KX-21N hematology analyzer were labeled with new expiration dates according to the manufacturer. Findings were: 1. Review of the "Maintenance and Supplies Replacement" section of the Sysmex KX-21N operator's manual (Revised October 1998) revealed that the expiration after opening for the Cell Pack reagent is 60 days. 2. Surveyor observations on 1/16/19 at 1110 hours in the laboratory revealed an in use Cell Pack (lot Y8297, exp 5/7/20) with no documentation of the opened or expiration date. 3. Review of the laboratory billing report from January 2018 to December 2018 revealed the laboratory performed 7356 CBC testing using the Sysmex KX21N hematology analyzer. Refer to patient alias list. 4. An interview with the primary testing person on 1/16/19 at 1130 hours in the laboratory confirmed the above findings.