

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2147528	<b>(X3) Date Survey Completed</b>  12/03/2019
<b>Name of Provider or Supplier</b>  South Bend Medical Foundation / Egh	<b>Street Address, City, State</b>  600 East Blvd, Elkhart, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to ensure four of six tissue marking dyes (blue, orange, red, green) were labeled with expiration dates. Findings included: 1. Review of policy/procedure titled: "Quality Control General Policies," approved by the Laboratory Director on 11-8-2018, read: "Discard all outdated reagents/label reagents/standards as applicable and appropriate, with the following elements...expiration date: MM/DD/YY..." 2. Review of "Frozen Section Room Cleaning" log for August, 2019 (reviewed/signed by the Laboratory Director on 9-23-2019); September, 2019 (reviewed/signed by the Laboratory Director on 10-11-2019); and November, 2019 (review/signature of Laboratory Director unavailable) indicated the following: a. A statement on the back of the logs which read: "Expiration date information...dyes as stated by manufacturer. If no date noted, 5 years after opening. b. The logs indicated "reagent labeling/expiration" was checked and found acceptable by SP3, Processor, on the following dates: 8-6-2019; 8-13-2019; 8-20-2019; 8-28-2019; 8-30-2019; 9-6-2019; 9-12-2019; 9-17-2019; 9-25-2019; 11-1-2019; 11-7-2019; 11-14-2019; 11-19-2019 and 11-26-2019. 3. On 12-3-2019 at 1:40 PM, while accompanied by SP1, Compliance and Regulatory Specialist, and SP2, Quality Systems Supervisor, the following was observed on the counter top, next to the microscope: a. An opened, 2 ounce (oz.) bottle of "CDI's Tissue Marking Dyes - Blue," lot number and expiration date were illegible. It was unable to be determined if the dye was expired. b. An opened 2 oz. bottle of "CDI's Tissue Marking Dyes -</p>

Orange," lot number and expiration date were illegible. It was unable to be determined if the dye was expired. c. An opened 2 oz. bottle of "CDI's Tissue Marking Dyes - Red," lot number and expiration date were illegible. It was unable to be determined if the dye was expired. d. An opened 2 oz. bottle of "CDI's Tissue Marking Dyes - Green," lot number and expiration date were illegible. It was unable to be determined if the dye was expired. e. There were no other bottles of blue, orange, red, or green "CDI's Tissue Marking Dyes" observed in the laboratory during the tour. 4. Review of patient records indicated the following: a. Patient #1 had one frozen section specimen processed and slides read on 7-10-2019. b. Patient #2 had two frozen section specimens processed and slides read on 9-16-2019. c. Patient #3 had one frozen section specimen processed and slides read on 9-20-2019. d. Patient #6 had one frozen section specimen processed and slides read on 8-21-2019. e. Patient #7 had one frozen section specimen processed and slides read on 10-17-2019. 5. On 12-3-2019 at 1:59 PM, SP1 and SP2 acknowledged the expiration dates were illegible. 6. Annual case volume = 7,765

**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, observation, and interview, the laboratory failed to ensure two of eight staining reagents (Toluidine Blue and acetic acid), and one of two bottles of disinfectant (Bleach-Rite Disinfecting Spray) did not exceed their expiration date. Findings included: 1. Review of policy/procedure titled: "Quality Control General Policies," approved by the Laboratory Director on 11-8-2018, read: "Discard all outdated reagents/standards immediately..." 2. Review of "Frozen Section Room Cleaning" log for August, 2019 (reviewed/signed by the Laboratory Director on 9-23-2019); September, 2019 (reviewed/signed by the Laboratory Director on 10-11-2019); and November, 2019 (review/signature of Laboratory Director unavailable) indicated the following: a. A statement on the back of the logs which read: "Expiration date information...Acetic Acid 1 year after made...Toluidine Blue 1 year after made..." b. The logs indicated "reagent labeling/expiration" was checked and found acceptable by SP3, Processor, on the following dates: 8-6-2019; 8-13-2019; 8-20-2019; 8-28-2019; 8-30-2019; 9-6-2019; 9-12-2019; 9-17-2019; 9-25-2019; 11-1-2019; 11-7-2019; 11-14-2019; 11-19-2019 and 11-26-2019. 3. On 12-3-2019 at 1:40 PM, while accompanied by SP1, Compliance and Regulatory Specialist, and SP2, Quality Systems Supervisor, the following was observed on the counter top, next to the microscope: a. An opened 500 milliliter (mL) squeeze bottle of acetic acid, lot number unknown, expiration date 9-17-2019, available for use. b. An opened 1000 mL bottle of acetic acid, lot number unknown, lot number unknown, expiration date 9-17-2019, available for use. c. A coplin jar filled with "Toluidine," lot number unknown, expiration date 8-18-2019, available for use. d. A 200 mL bottle of "toluidine Blue," lot number "143118," expiration date 8-18-2019, available for use. e. A 32 ounce (oz.) spray bottle of "Bleach-Rite Disinfecting Spray," lot number unknown, expiration date 8-7-2019, available for use. f. There were no other bottles of acetic acid or toluidine blue observed in the laboratory during the tour. 4. Review of patient records indicated the following: a. Patient #2 had two frozen section specimens were processed and slides read on 9-16-2019. b. Patient #3 had one frozen section specimen

processed and slides read on 9-20-2019. c. Patient #6 had one frozen section specimen processed and slides read on 8-21-2019. c. Patient #7 had one frozen section specimen processed and slides read on 10-17-2019. 5. In interview on 12-3-2019 at 1:59 PM, SP1 and SP2 acknowledged the expired staining reagents and disinfectant. 6. Annual case volume = 7,765