Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0927504	09/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Community Surgery Center North	8040 Clearvista Pkwy Ste 150, Indianapolis, IN	

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
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on document review and interview the laboratory failed to document performance specifications in their Risk Assessment for one of one assay (Serum Beta Pregnancy Testing) reviewed, to verify and support the change to running monthly external quality control. Findings Include: 1) Review of policy titled, "LAB-SURE VUE SERUM URINE," revised date of "07/17", no laboratory director signature indicated, read on page two under the quality control section, "...External Controls Serum controls should be used when testing serum. Negative and positive controls for hCG should be tested according to federal, state, and local authorities. Quality control should be performed on each lot received, and monthly..." 2) Review of package insert titled, "Sure-Vue Serum/Urine hCG-STAT...," published date of 2012, read on page one under "External Procedural Controls...," "It is recommended that federal, state, and local guidelines be followed..." 3) Review of the Risk Assessment for Serum Beta Pregnancy Testing indicated no performance verification had been completed to verify the accuracy of patient testing with a change to running quality control monthly. 4) Medical record review indicated the following patients (ten of ten reviewed) had serum pregnancy testing performed with positive and negative controls being run monthly and having no verification data to support this frequency in their IQCP (Individualized Quality Control Plan): a. PT#1/10-16-17/Neg (Negative result) b. PT#2/11-22-17/Neg c. PT#3/12-12-17/Neg d. PT#4/12-15-17/Neg e. PT#5/11-16-17/Neg f. PT#6/1-23-18/Neg g. PT#7/2-20-18/Neg h. PT#8/3-1-18/Neg i. PT#9/6-12-18/Neg j. PT#10/5-31-18/Neg 5) In interview on 9/10/18 at 11:42 am, SP-2 confirmed the above patients had serum pregnancy controls run monthly and did not have

	performance specification verification data listed in their IQCP to support a frequency other than two different levels of quality control being run every day of patient testing (federal regulation).