

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2011351	(X3) Date Survey Completed 10/03/2022
Name of Provider or Supplier Indiana Orthopaedic Hospital, Llc	Street Address, City, State 1260 Innovation Pkwy, Greenwood, 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
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 observation, record review and interview, the laboratory failed ensure three of six blood tubes (expiration date 7/31/2022) were not expired. Findings included: 1. During a tour of the in-patient station on 10/3/2022 at 9:00 AM, revealed an open bag of blood collection tubes stored in a cabinet. Three out of six blood collection tubes used for sending out testing had expired on 7/31/2022. 2. Review of "Stock Rotation and the management of Clinical Products with Expiration Dates", approved on 8 /2022, stated "All clinical products with an expiration date or with a manufactured date of greater than (5) years will be reviewed on a monthly basis to insure that expire products or soon to expire products are removed and isolated, so they are not used. 3. During an interview on 10/3/2022 at 9:04 AM, SP#4 (testing person) confirmed three 6 blood tubes in the cabinet had expired on 7/31/2022.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to perform six-</p>

month competency assessment in 2021 for one (SP#3) out ten testing personnel reviewed. Findings included: 1.) Review of CMS-209 laboratory Personnel Report revealed SP#3 as testing person and technical consultant (TC). 2.) Review of personnel competency records revealed SP#3 had an initial competency assessment done on 1/28/21 and annual competency assessment on 2/18/22. There was no documentation of a six- month competency for SP#3 in 2021. 3.) Review of "i-Stat" policy, effective date 8/22, stated "1. All operators will complete initial i-stat training upon hire, six (6) month training and year one." 4.) During an interview on 10/3/2022 at 1:54 AM, SP#1 (Director of Point of Care (POC)) and SP#2 (POC specialist) confirmed six- month competency assessment was not completed for SP#3 in 2021.