Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0857296	11/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Beck Analytical Services Llc	3209 W Smith Valley Rd Ste 222, 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
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on observation, document review, and interview, the laboratory failed to ensure one of two individuals reviewed (SP 3), performing high complexity testing, qualified as a testing person (TP). Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical

laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on observation, document review, and interviews, the laboratory failed to ensure one of two individuals reviewed (SP 3), performing high complexity testing, qualified as a TP. 1. On 11/21/19 at 9:15 AM, SP 3 was observed operating a "wild heerbrugg" microscope. 2. Review of "Laboratory Personal Report (CLIA)" form (CMS-209), signed by SP 1 (laboratory director) on 11-18-2019, indicated SP 3 was a TP. 3. Review of personnel records indicated SP 3 had a "Technical Certificate" with a major/concentration in practical nursing. 4. Review of "Laboratory Personnel Competency Review" documents for SP 3, dated 11/08/17, 10/02/18, and 10/03/19, and signed by SP 2 (general supervisor) and SP 3, read, "performs high complexity only under the onsite, direct supervision of a general supervisor qualified under Sec. 493.1461". 5. In interview on 11/21/19 at 9:55 AM, SP 3 indicated they had a certificate as a licensed practical nurse (LPN) and had been working at the lab for ten years. 6. In interview on 11/21/19 at 1:50 PM, SP 2 indicated SP 3 operates the microscope and the spectrometer under SP 2's supervision. SP 2 acknowledged SP 3

	is a licensed practical nurse, and has been working at the lab for ten years. 7. Review of "Responsibilities - Testing Personnel" for SP 3, dated 11/25/19 and signed by SP 2 and SP 3, indicated job duties include: "Specimen Physical Characteristics (SIZ) procedure", and the "Infrared Microscopy (IRS) procedure". 8. "SIZ Procedure Manual", signed and dated 06-01-09 by SP 1, read "The SIZ test procedure is performed on every specimen received by Beck... It determines the gross physical dimensions, count and mass". 9. "IRS Procedure Manual", signed and dated 02-01-10 by SP 1, included preventative maintenance, calibration, quality control, and procedures for the Infrared Spectrometer (IRS). 10. Review of Enclosure 1, signed and dated by SP 1 on 11/18/19, list the microscopy (high complexity) annual test volume of 6500, and the spectroscopy (high complexity) annual test volume of 6500.