

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0861378	<b>(X3) Date Survey Completed</b>  01/17/2019
<b>Name of Provider or Supplier</b>  Oncology Consultants	<b>Street Address, City, State</b>  2130 W Holcombe Blvd 10th Floor, Houston, TX	
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>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D5475</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records, laboratory patient records, and confirmed in interview, the laboratory failed to perform positive and negative staining controls each day of testing for the flow cytometry testing on the Beckman Coulter Navios flow cytometer. Findings were: 1. Review of the laboratory records revealed the laboratory performed flow cytometry evaluating the following 29 markers: CD2 CD3 CD4 CD5 CD8 CD10 CD11b CD13 CD14 CD16 CD19 CD20 CD22 CD23 CD33 CD34 CD38 CD45 CD56 CD57 CD64 CD103 CD117 FMC7 HLA-DR Surface kappa Surface lambda 7-AAD 2. Review of the laboratory quality control records from 08/2018 to 01/2019 revealed the laboratory performed positive and negative staining controls using the Streck CD Chex quality control monthly on 08/10/18, 09/18/18, 10/18/18, 11/12/18, 12/12/18, and 01/15/19. 08/10/18 lot 81900041 , exp 10/06/18 09/18/18 lot 81900041 , exp 10/06/18 10/18/18 lot 82460041, exp 12/01/18 11/12/18 lot 82460041, exp 12/01/18 12/12/18 lot 83020041, exp 01/26/19 01/15/19 lot 83020041, exp 01/26/19 3. Random review of the laboratory patient records</p>

from 08/2018 to 01/2019 revealed the laboratory performed patient testing without daily positive and negative staining controls for the following days the laboratory performed patient testing. 01/04/19 MR 258337 12/18/18 MR 246734 12/06/18 MR 256967 11/30/18 MR 256758 11/14/18 MR 73714 10/05/18 MR 256214 09/20/18 MR 248991 08/09/18 MR 254348 08/03/18 MR 253718 10/31/18 MR 43003 4. Review of the laboratory quality control records revealed no documentation of an IQCP (Individualized Quality Control Plan) to reduce the frequency of the positive and negative staining controls to once monthly. 5. An interview with the technical supervisor on 01/17/19 at 1450 hours in the conference confirmed the above findings. She was unaware that the laboratory was required to perform the key: CD2 - cluster of differentiation 2 CD3 - cluster of differentiation 3 CD4 - cluster of differentiation 4 CD5 - cluster of differentiation 5 CD8 - cluster of differentiation 8 CD10 - cluster of differentiation 10 CD11b - cluster of differentiation 11b CD13 -cluster of differentiation 13 CD14 - cluster of differentiation 14 CD16 - cluster of differentiation 16 CD19 - cluster of differentiation 19 CD20 - cluster of differentiation 20 CD22 - cluster of differentiation 22 CD23 - cluster of differentiation 23 CD33 -cluster of differentiation 33 CD34 -cluster of differentiation 34 CD38 -cluster of differentiation 38 CD45 - cluster of differentiation 45 CD56 - cluster of differentiation 56 CD57 - cluster of differentiation 57 CD64 - cluster of differentiation 64 CD103 - cluster of differentiation 103 CD117 -cluster of differentiation 117 FMC7 -epitope of CD20 HLA-DR - Human Leukocyte Antigen-antigen D Related 7-AAD - 7-aminoactinomycin D

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control records, laboratory patient records, and confirmed in interview, the laboratory quality assurance failed to detect failures in the analytic systems. Refer to D5475

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control records, laboratory patient records, and confirmed in interview, the technical supervisor failed to ensure the laboratory established and maintained a quality control program for the flow cytometry testing on the Beckman Coulter Navios flow cytometer. Refer to D5475