

Human Papillomavirus (HPV) Testing at ChristianaCare

The Molecular Lab follows two paths for Human Papillomavirus (HPV) testing for patients 25 years or older: the traditional path of cytology followed by HPV testing, known as co-testing, or the alternative path of HPV Primary Screening with reflex to Cytology.

For the HPV Primary Screening path, samples are routed to the Molecular Lab for Polymerase Chain Reaction (PCR) testing. The test detects the DNA of HPV types 16 and 18, along with a pooled group of twelve other high-risk HPV types. A positive, negative, or indeterminate result will be given for each, with all results available in the Electronic Health Record immediately upon result sign out.

If the HPV PCR testing is positive, then the sample will reflex to the Cytology Lab for Pap Smear. After the Pap Smear is performed, the full Cytology report will be available.

If a sample results as indeterminate for HPV, testing is repeated. If the sample yields indeterminate results again, then an indeterminate result is reported. Indeterminate HPV Primary Screening samples will reflex to the Cytology Lab for Pap Smear.

The average result turnaround time from the time the sample is received in the Molecular Lab to posted HPV result is about three days. This result, in combination with the Cytology result, enables the patient and their care team to begin quickly planning next steps for treatment in the case of abnormal results.

HPV Statistics at ChristianaCare:

Test volume in 2022: 1,493

Test volume in 2023: 1,830

Test volume in 2024: 2,033

Estimated 2025 volume: Over 2,100 tests performed

Average positivity rate 2022-2025: 17.4% of samples tested positive for HPV

Roche cobas 4800 instrument used for HPV testing



Updates from our Laboratories.....

Microbiology....

Candida auris Screening to be Brought in House

Microbiology is excited to introduce in-house screening for patients at high risk of being colonized with *Candida auris*. *Candida auris* is a globally emerging pathogen associated with healthcare-related infections, particularly in patients with underlying medical conditions, prolonged hospitalization, or exposure to invasive medical devices. Screening protocols are crucial for infection prevention and patient management as the yeast is found to survive on various environmental surfaces and exhibit resistance to multiple classes of antifungal drugs commonly used to treat fungal infections. Coming soon, screening of patients for *Candida auris* will be performed in-house using the DiaSorin Molecular PCR test, creating a more rapid turnaround time to assist in bed management, infection prevention practices, and potentially allowing the number of patients screened to be expanded.

General Laboratories....

The General Laboratory collaborated with Microbiology, Laboratory Information Services, Infection Prevention, Pharmacy, Nursing, Information Services, Emergency Medicine and Medicine departments to implement new evidence-based reflex criteria for urine cultures: WBC count of >10 cells (>5 for pediatric patients <24 months). The laboratory made necessary changes to the urinalysis (UA) standard operating procedures, UA with Reflex to Culture (UARC) order in PowerChart and UARC rules in the laboratory information system on August 15, 2023.

Several months after the change, the multidisciplinary team conducted a retrospective cohort study to assess the clinical, operational and financial impact of the change using EHR data, comparing the pre-implementation period of 12/15/22-8/14/23 to the post-implementation period of 8/15/23-4/15/24. The study results showed that the percentage of UAs that reflexed to culture from UARC orders decreased by 37% ($p < 0.001$) for orders from all settings and 35% ($p < 0.001$) for orders from the ambulatory setting after the criteria change. The culture positive rate of all urine cultures reflexed from UARC increased by 26% ($p < 0.001$) after the change reflecting a more efficient testing operation. Furthermore, the UARC criteria change led to a 31% (\$65,000) decrease in the cost associated with urine cultures on inpatient visits during the study period.

This project was submitted to the 2024 ChristianaCare Way Awards where it won the Value Award and the People's Choice Award. Furthermore, an abstract of this study was submitted to the 2025 American Society for Clinical Pathology (ASCP) Annual Meeting poster presentation session being held in Atlanta between November 17 to November 20, under the lab stewardship category. We are pleased to share that our poster has been selected for the meeting which will allow us to showcase ChristianaCare's impactful lab stewardship initiative at a national level.

Point of Care....

Accu-Chek Automated Competency Assessments

Point of Care Laboratory (POC LAB) is pleased to share that the inaugural (March 2025) effort made to automate AccuChek Annual Competency Assessments was ultimately a success. This project involved an interface from the Learning Space to our POC LAB middleware software (QML) which manages operator certification for AccuChek. It should be noted this project required all nursing personnel to commit to complete AccuChek annual competency within a specific month in the calendar year; and our nursing colleagues chose March.

While we definitely had a few hiccups/ bumps in the road, we are wrapping up the effort for this year with nearly all users active achieving recertification! Lessons have been learned which are sure to make next year's process a huge success! POC LAB certainly appreciated all the patience and understanding exhibited from our nursing friends as we worked throughout this new process.

Q & A

TRBC1 Testing in Flow Cytometry

What is TRBC1 and what is its significance in the diagnosis of T-Cell neoplasms?

T-cell receptor beta constant 1 (TRBC1) is a protein expressed on the surface of some T-Cells. It is part of the TCR $\alpha\beta$ -CD3 complex, and the addition of the antibody is useful for the detection of T-cell neoplasms.

How does Flow Cytometry utilize TRBC1?

Within the last few years, a monoclonal antibody specific for TRBC1 was discovered. Since then, a flow cytometry strategy to assess T-cell clonality was developed. TRBC1 specific antibodies such as the JOVI-1 clone are used in combination with other markers to identify and characterize T-cell subsets, including those involved in lymphomas.

What is TRBC1 role in T-Cell Clonality?

In the process of TCR β gene rearrangement, only two constant regions are expressed. TRBC1 and TRBC2. Similarly to kappa/lambda light chains for B-cell clonality assessment, TRBC1 provides the possibility to detect clonality within the distinct CD3+ T-cells. Normal polytypic $\alpha\beta$ T-cell expression exhibits a comparable number of TRBC1-positive and TRBC1-negative T-cells. However, $\alpha\beta$ T-cell neoplasms either display monotypic TRBC1 expression or lack TRBC1 expression.

What are some pitfalls to avoid with TRBC1?

TRBC1 is only expressed on mature $\alpha\beta$ T-cells, so it's crucial to exclude any $\gamma\delta$ T-cell populations in the analysis to prevent mistakenly interpreting it as TRBC1-negative. Additionally, it is important to recognize that clonal populations of T-cells may be seen in reactive conditions as well as T-cell neoplasms. So, the presence of these populations must correlate with the other aspects of the clinical picture.

When will Christiana offer TRBC1 testing in Flow Cytometry?

The addition of TRBC1 provides a quick, reliable, and inexpensive method for T-cell clonality assessment. We have started the validation process with the hope to include this in addition to our Leukemia/Lymphoma Immunophenotyping panel in the near future.

If you have any laboratory questions or suggestions for future LabScope Q&A sections, you can submit it here:

[Laboratory Q&A Submission Form](#)

Picture of the Month

The arrow points to a blast in peripheral blood smear visualized by CellaVision digital microscopy. Blast generally has a large nucleus, immature chromatin, a prominent nucleolus, scant cytoplasm and few or no cytoplasmic granules. Circulating blasts are rare but can be seen with severe infections, medications (e.g. granulocyte colony stimulating factor), bone marrow replacing processes and hematopoietic neoplasms.

