LabWire

Laboratory News and Analysis for Clinicians July 2021

Lab systems update: Our systems are changing!

Bronson has begun our project to replace our Laboratory Information System (LIS), implementing Epic's Beaker application as the main LIS. We are also implementing a new blood bank system (SafeTrace Tx by Haemonetics), and many aspects of our instrument controls.

This change in lab systems are expected to bring us additional functionality to allow for improved workflows, while reducing operational costs. Providers using Epic will have increased insight into lab results.

Countdown:

312 DAYS

Go-live for the new systems are May 15, 2022

What to anticipate with the new Epic Beaker system:

Using Epic Beaker, Bronson will be able to print "instrument ready" specimen labels at the point of collection for all inpatient and clinical specimens, which will help enhance specimen identification and turnaround measures.

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Lab medical directorship in the clinic: A refresher on the basics

By Erika Deaton-Mohney MT(ASCP), CPP and Dr. Ellen Flatley MD, FCAP

Laboratory tests performed within our system's outpatient clinics fall into two categories: waived testing and provider performed microscopy. This article will focus on waived testing and is intended for clinician lab medical directors.

Designation as a waived test is assigned by the FDA to laboratory test methods that meet specific criteria for ease of use and have low risk of patient harm. This test classification was created under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88, or simply CLIA). The term *waived* is used because there is no routine regulatory oversight, in contrast to our moderate and high complexity laboratory sites. The Centers for Medicare and Medicaid Services (CMS), on rare occasions, does perform regulatory oversight in the waived laboratory setting. This includes the possibility of an inspection, for example, after a formal complaint has been received.

Even though these tests are generally robust, they are not without the potential for error, and the ability to cause serious patient harm. To decrease the likelihood of incorrect results, waived testing needs to be performed correctly, by trained personnel and in an environment where good testing practices are followed. Due to this, there are still several requirements that CMS, under the jurisdiction of the CDC, the FDA and CMS itself require:

- Obtain a Certificate of Waiver (CW)
- Pay biennial certificate fees
- Follow manufacturers' test instructions

Enter the Point of Care Team within the Bronson Laboratory. We are a group of laboratory professionals with a passion for laboratory excellence and a profession of laboratory compliance. We've partnered with your practice manager to obtain and maintain the CW. Our oversight provides education for practices to perform self-inspections to ensure patient testing is safe and reliable. The next article in this series will expand on this, so that you know how your team can ensure *your* laboratory is producing quality patient test results.

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Ordering a 'pathologist smear review' for lymphopenia will not be helpful

By Dr. Ellen Flatley, MD, FCAP, hematopathologist

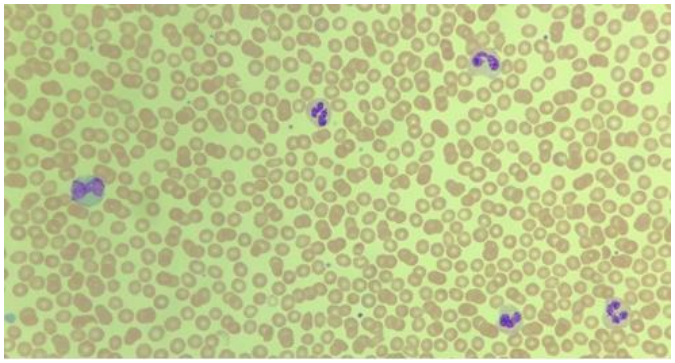
Causes of lymphopenia include acquired and inherited etiologies, with examples listed below.

Acquired	**Inherited**
Acute stress, such as: trauma, surgery, burns, severe acute illness	SCID
Acute infection	CVID
Chronic infections (AIDS, Whipple disease)	Reticular dysgenesis
Chronic inflammatory disorders (SLE, sarcoidosis)	Swiss-type agammaglobulinemia
Protein-calorie malnutrition	DiGeorge syndrome
Cushing syndrome and corticosteroid therapy	Ataxia Telangiectasia
Immunosuppressive therapy (e.g. azathioprine, cyclosporin)	Wiskott-Aldrich syndrome
Anticancer chemotherapy or radiotherapy	
Aplastic anemia	
Acute and chronic renal failure	
Malignancies (e.g. advanced carcinoma)	

Hematopoietic stem cells reside within our bone marrow, however, lymphocytes spend the vast majority of our lives patrolling elsewhere and for practical purposes do not renew to any significant degree in the bone marrow, unlike our myeloid cell lines. After going through the thymus in our younger years, T-cells live in our blood, lymph nodes, spleen, GI system and elsewhere whereas B-cells frequently differentiate in lymph nodes, while also residing there in addition to our blood, spleen, tonsils and elsewhere.

While erythroid, neutrophil or platelet cytopenias may reflect pathologic processes in the marrow, this is not really true for lymphocytes. They also don't acquire dysplastic changes like the myeloid lineage. And, when they turn neoplastic, if they do go into the peripheral blood their numbers increase, not decrease.

All this to say, when a patient has a lymphopenia there is no value added in obtaining a peripheral smear review by Pathologist.



This patient has lymphopenia.
There are no lymphocytes in this field.

Reference:
Bain BJ. (2001).Chapter 2 White Blood Cells, Table 2-4, In SL. Jones (Ed.), Clinical Laboratory Pearls, (p131). Philadelphia, PA: Lippincott Williams and Wilkins

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Leukocyte changes in MIS-C patients captured & reported on a CBC with differential

By Dr. Ellen Flatley, MD, FCAP, hematopathologist

Provider orders for a blood smear review by pathologist with a stated indication of "MIS-C" have been coming in with regularity. This article suggests a change in practice.

MIS-C, or multisystem inflammatory syndrome in children (MIS-C) is a constellation of signs and symptoms similar to Kawasaki disease with evidence of recent COVID-19 infection or exposure. The entity is strictly defined by the Centers for Disease Control and Prevention (CDC), but cut short in this article for brevity (web link below).

The medical literature also includes findings seen in leukocytes, namely an increase in immature neutrophils and neutrophils with toxic changes (Paolino J). Toxic changes in the neutrophil lineage include: prominent cytoplasmic granules (primary granules), multiple vacuoles in the neutrophil's cytoplasm and/or the presence of Döhle bodies. The cited article describes these changes in three children in Boston with MIS-C, in which pediatric oncologists performed manual smear reviews. It should also be noted this is a common change seen in reactive, inflammatory, infectious or therapeutic situations.

At Bronson, we have state-of-the-art hematology analyzers and dedicated, well-trained medical technologists, which allows us to consistently report both of these parameters.

The hematology analyzers are able to quantify neutrophils and immature neutrophils. The term immature neutrophils encompasses the promyelocyte to metamyelocyte maturation pathway. As you are aware, blasts are designated separately. The analyzers have been carefully programmed to trigger manual review for a number of findings/possible findings that require technologist confirmation. A technologist will review key images of the blood smear and/or the blood smear itself and categorize them appropriately. This is how morphologic findings are reported and graded, such as a report of "2+ toxic granulation".

An additional layer of quality assurance is the auto-generated pathologist review triggers that we have in place within our lab middleware. For MIS-C patients triggers such as absolute neutrophils < 0.5x 10(9)/L, monocytosis > 3.0 x 10(9)/L, and any blasts present would appropriately triage smears for pathologist comment or confirmation. Technologists will also share smear reviews if what they see warrants further review. Peripheral smears ordered with a submitted indication of "MIS-C" recently have included mild or moderate left shifted neutrophilias, mild thrombocytopenias and normal neutrophil counts; these type of smear reviews have no added value from Pathologist review.

Further, review of an internet published pathway for MIS-C patients from Children's Hospital of Philadelphia, an esteemed children's hospital, does not include ordering of a blood smear review by a pathologist (web link below).

Finally, CBC with differentials have inpatient turn-around-times measured in minutes. Pathologist smear reviews, however, in the absence of emergency situations (which require a call with the appropriate pathologist), are reviewed and reported during business hours on a rolling basis.

It is suggested going forward to rely on the CBC with differential data and discontinue ordering peripheral blood smear review by a pathologist.

References:
Distributed via the CDC Health Alert Network. Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19) https://emergency.cdc.gov/han/2020/han00432.asp Accessed 24 May 2021.
Paolino J, Williams DA. Peripheral blood smears of children with multisystem inflammatory syndrome demonstrate prominence of early myeloid forms with morphologic evidence of toxic change. Pediatr Blood Cancer. 2021;68(1):e28551. doi:10.1002/pbc.28551 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7404579/
Emergency Department, ICU and Inpatient Clinical Pathway for Evaluation of Possible Multisystem Inflammatory Syndrome (MIS-C) https://www.chop.edu/clinical-pathway/multisystem-inflammatory-syndrome-mis-c-clinical-pathway Accessed 24 May 2021.

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