The department of pathology is proud to present this edition of the Path-O-Gram (POG). This POG newsletter was previously edited by Dr. Frank Wians, and I am honored to assume the editor duties. The publication and distribution of the POG will be approximately 3-4 times each year, or as warranted. We believe that the content will be valuable to everyone in our system who take care of patients. The POG will contain information on general pathology news, educational discussions related to pathology specialties, and important announcements about changes in clinical testing as well as other pathology services.

Dr. Jude Abadie, POG editor
of large datasets using the R programming language. Dr. Geno looks forward to continuing his career in laboratory medicine at TTUHSC and UMC, where he will direct the microbiology laboratory and provide medical education to students in the charge of TTUHSC and UMC.

Jonathan Lavezo, M.D.
Assistant Professor of Pathology

Dr. Jonathan Lavezo grew up in Denton, Texas where he completed a Chemistry and Biochemistry double major at the University of North Texas. He went on to attend El Paso’s own Paul L. Foster School of Medicine graduating in 2015. Dr. Lavezo did his residency and fellowship training at Stanford University where he completed a combined program in Anatomic Pathology and Neuropathology, as well as an additional year of surgical pathology fellowship focusing on head and neck, cardiothoracic, and soft tissue pathology. At TTUHSC/UMC Dr. Lavezo will work closely with the pathologists, neurosurgeons, neurologists, and psychiatrists to provide high-quality diagnostic neuropathology. He will also focus on teaching neuropathology to medical trainees and staff, in addition to promoting collaborative neuropathology related research.

Jude Abadie, Ph.D., DABCC, FAACC, DABMGG, FACMG
Associate Professor of Pathology

Dr. Jude Abadie grew up in New Orleans, Louisiana where he graduated from LSU Health Science Center with a doctorate in pathology. He is fellowship-trained and board certified in clinical chemistry, clinical toxicology, and clinical molecular genetics. During the last 21 years Dr. Abadie was active duty Army, where he served in laboratory medicine leadership positions at several our nation’s military medical centers, including Walter Reed in Washington DC, Tripler in Hawaii, and Brook Army Medical Center in San Antonio, TX. He has held a lifelong passion for teaching and working in the field of laboratory medicine. At TTUHSC/UMC, Dr. Abadie’s main focus will be on clinical laboratory testing operations, clinical consultant/director to our outlying clinics, and providing graduate as well as undergraduate medical education.

I’m very pleased that we were successful in those key faculty recruitment. I wish to thank all our faculty and staff. We appreciate your flexibility and steadfast support to each other and our department particularly during this very taxing time. Having these new brilliant faculties joining us is a testament to the tremendous positive momentum that our university is displaying, despite the global COVID 19 pandemic. To the new faculty: we welcome you to be part of a great and exciting environment as you seek opportunities to practice state of the art pathology and grow in your academic career.
II. Anatomic Pathology

Robust histology instrumentation to improve neuropathologic diagnoses

Dr. Jonathan Lavezo

University Medical Center (UMC) Laboratory, Division of Anatomic Pathology focuses on the gross and microscopic evaluation of surgical specimens and tissue biopsies. The histology section plays vital roles processing and preparation of tissue for microscopic evaluation. Our new histology supervisor, George Sherrod, has been pivotal in upgrading and improving the functionality of the Histology Lab. George has overseen the installation of two new instruments. One instrument stains slides with Hematoxylin and Eosin (H&E) for routine histology, and another stains slides for immunohistochemical (IHC) evaluation of tissue proteins.

Features of the Leica Spectra instrument:

- Validated for H&E staining on surgical specimens
- Improving differentiation of cell types and cytologic characteristics in tissue sections
- Used in determination of neuron viability (Image 1 – living; Image 2 – dying)
- Post-mortem evaluation of brain tissue from an ischemic stroke shows characteristic ‘red dead’ neurons (Image 2)

Image 1: Viable cerebellar Purkinje neuron with basophilic cytoplasm, open chromatin, and prominent nucleolus

Image 2: Dying neuron with eosinophilic (red) cytoplasm and dark pyknotic nucleus

Features of the Leica Bond-III instrument:

- Uses chromogen IHC to identify proteins by marking them as either red or brown
- Facilitates the myosin double stain, where two different color antibodies create a mosaic pattern to highlight different myosin fiber types (Image 3).¹
- Currently being optimized and validated for clinical use.

Image 3: Myosin double stain highlighting Type I (Brown), Type 2A (Red), and Type 2X (Blue) myofibers

As a pathologist, the use of IHC is often critical to making the correct diagnosis. The most accurate diagnoses will help clinicians when selecting treatment plans and determining patient prognosis. IHC can also be used to detect specific mutations in primary brain cancers, such as mutations of the enzyme isocitrate dehydrogenase (IDH) in gliomas. IDH1 R132H is the most common point mutation in IDH-mutated gliomas and is required for definitive classification of gliomas according to the World
Health Organization. Soon after validation of the Leica Bond instrument, the IDH1 R132H antibody will be added to the diagnostic repertoire at UMC, bringing us to the front of diagnostic neuropathology in El Paso, Texas.


For more info contact Dr. Jonathan Lavezo: 915 996-4956

III. Clinical Pathology News

- Three laboratory tools to improve quality for providers and patients: Changes are coming!
  Dr. Jude Abadie

NOTE: Two important changes to be implemented on Monday, 14 December 2020

1. Changes to the acceptable body fluid types and body fluid analytes for in-house testing
2. Changes to critical (immediate action) analytes and values

Laboratory Quality Topic Part 1 of 3: Body Fluids:

Changes stated below to be implemented on 14 December 2020

On 14 December 2020, the only body fluid tests (other than CSF, serum, plasma, and urine) that will be performed in-house will be limited to the fluid types and analytes listed in Table 1. These were discussed and coordinated in conjunction with department chiefs and provider at UMC/TTUHSC.

<table>
<thead>
<tr>
<th>Assay Description</th>
<th>Peritoneal</th>
<th>Pleural</th>
<th>Synovial</th>
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<tr>
<td>1 Albumin</td>
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<td>10 Triglyceride</td>
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<td>11 Uric Acid</td>
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Table 1. Body fluid testing menu offered in-house at UMC/TTUHSC starting 14 December 2020

The UMC laboratory recently reviewed the menu of body fluid tests in the context the College of American Pathologists (CAP) regulatory compliance.

The outcome of this review included:

- A proposal to modify our current body fluid tests to better align with CAP compliance
- A technical pathway for implementing our new clinical chemistry platform that will replace the current platform in 2022

To implement body fluid testing, specific regulatory requirements must be met. Body fluid validations must be performed as laboratory developed tests (LDTs) when the vendor/manufacturer does not support the test as a test that has been granted approval to be performed on serum or plasma. This can be illustrated using glucose as an example:

- Serum glucose testing is supported on our instrumentation through FDA and other regulatory approval.
- However, the vendor makes no claims on the accuracy of glucose in other types of body fluid such as synovial, cyst, or peritoneal fluids.
Therefore, the unsupported matrices must undergo LDTs.

LDTs for body fluid tests (i.e., body fluid types and analytes) will require the following validations:

- **Accuracy**: Ability of the assay system to correctly measure the analyte
- **Precision**: Ability of the assay system to reproduce the same value on the same sample
- **Linearity**: Ability of the assay system to generate a line along a range of reportable sample values with an acceptable r-value and equation of the line \( y = mx + b \).
- **Analytical measurable range**: Ability of the assay system to measure values through a range of values to generate reportable patient results that are accurate and precise.
- **Maximal dilution/reportable ranges**: Ability of the assay system to extrapolate accurate concentrations and generate reportable patient values that are accurate and precise.
- **Reference intervals**: Verifying or establishing values considered “normal” for our reference population
- **Analytical sensitivity**: Ability of the assay system to distinguish an analyte concentration from background noise
- **Analytical specificity**: Ability of an assay system to measure only the specific analyte in a sample
- **Stability**: Ability of an assay system to accurately measure analytes in a sample that has been exposed to variabilities such as temperature and time since collection

**Additional studies may include:**

- **Interference**: Determination the extent and magnitude that a drug could affect a result
- **H.I.L**: Determination of the extent and magnitude that Hemolysis, Icterus, and/or Lipemia could affect a result.

The studies listed above must be conducted for each analyte in each body fluid type. This equates to over 250 analytical studies to be validated when applied to the 23 tests in the three different body fluids listed in Table 1.

The menu (Table 1) has been developed to allow for optimal management of LDT validations for these body fluids as well as to encompass the most common body fluids clinically tested. This table/menu will be implemented on **14 December 2020**, and other body fluid testing, if offered, will be directed to the appropriate reference laboratory for testing. For example, carcinoembryonic antigen (CEA) in pancreatic cyst fluid is a body fluid and test not listed in Table 1 but is offered as a send-out test. The send-out reference laboratory has validated CEA in pancreatic cystic fluid, and the expected turn-around time will be 1-3 business days.

For the reasons describe above, as of 14 December, test orders on body fluids will be acceptable within the confines of Table 1 and for acceptability by the reference testing laboratory.

It is important to note that consideration of the order type will be dependent upon the provider order-entry request. For example, peritoneal fluid is often collected via paracentesis. Therefore, peritoneal and paracentesis fluid can be considered identical. Peritoneal fluid could also be collected during surgery or from tubes and drains. Instead of ordering fluids as a “JP drain”, the order would have to state “peritoneal” for one of the validated analytes.

In most clinical instances, chloride levels in body fluids mimic serum chloride and provides little added value\(^1,2\). This is also true for a majority of body fluid electrolytes\(^3\). Therefore, it is generally not recommended to establish LTDs for electrolytes in body fluids.

**Remember:**

- It is sufficient for laboratories to verify (vs. conducting full LTD studies) vendor performance claims for FDA-approved tests such as CSF total protein, CSF glucose, as well as other routine analytes routinely tested in serum, plasma, or urine.

Where the manufacture makes no performance claims on body fluids and analytes such as the 23 combinations listed in Table 1, CAP requires that full LTD validations are conducted prior to testing and disposition of results.
References:


Laboratory Quality Topic Part 2 of 3: Critical values/immediate action values:

Changes to be implemented 14 December 2020.

Upon recent review of the pathology department’s “Immediate action values” some analytes and critical value designations have been revised. The changes listed below, in a similar fashion as the changes in body fluids, were discussed with the department chiefs and other UMC and TTUHSC opinion-leaders. The changes listed below are intended to improve the value and quality of patient care through better laboratory practices.

- **Change 1 of 5:** Addition of an immediate action value of \( \geq 100 \, \mu \text{mol/L} \) for ammonia.
  - Increasing ammonia levels is the major contributor to cerebral edema in acute liver failure.
  - Sustained ammonia levels of 150 – 200 \( \mu \text{mol/L} \) significantly increases intraneuronal osmolarity and risks for intracranial hypertension and encephalopathy.
  - Significantly elevated ammonia values are also present in a variety of inborn errors of metabolism that may be undiagnosed or unexpected at presentation in some pediatric populations.
  - Adding this critical value to our list will have minimal little to no impact on lab tech time in calling the values to providers. This is due to a low number of expected ammonia values \( \geq 100 \, \mu \text{mol/L} \). Patient outcome, however, could be considerable (life-saving) with earlier detection.

- **Change 2 of 5:** Remove critical calls for high and low osmolality values.
  - About 25% of 623 hospital labs surveyed have a critical value for osmolality\(^1\).
  - Osmolality is usually followed in conjunction with electrolyte imbalances, such as sodium, critical values for osmolality in addition to electrolytes may not be of added value.
  - Critical values for osmolality are not called by many US facilities, to include the military’s only level 1 trauma center (BAMC), Mayo, or ARUP laboratories.
  - Removing osmolality as a critical value will improve patient care by allowing lab techs to focus on other testing needs and other critical calls.

- **Change 3 of 5:** Adjust the high critical call for sodium from \( \geq 155 \, \text{mmol/L} \) to \( \geq 160 \, \text{mmol/L for in-patients only} \).
  - The critical high value for sodium will remain \( \geq 155 \, \text{mmol/L} \) for out-patients.
  - Only in-patient sodium values will be changed to \( \geq 160 \, \text{mmol/L} \).
  - Keeping the critical high value at \( \geq 155 \, \text{mmol/L} \) for out-patients will allow closer/more immediate follow-up for patients with hypernatremia who are not already being monitored as an in-patient.
  - For in-patients, sodium levels \( \geq 160 \, \text{mmol/L} \) is supported as the high-critical value by many major US facilities, to include Brooke Army Medical Center, Stanford, ARUP, and Mayo.
  - Howantz et. al., reported that 160 mmol/L was the identified mean critical high sodium value cited for notification by 623 hospital labs surveyed\(^1\).
  - This change in the sodium critical value will allow the laboratory to focus more efforts on patient testing.
- **Change 4 of 4**: Add a critical high value for CK ≥ 10,000 IU/L.
  - Adding this critical value will alert providers of possible rhabdomyolysis, and when used in conjunction with myoglobin, can help in the care for patients who may have crushing injury or in cases of heat casualties.

- **Change 5 of 5**: Add a 2nd call for critical troponin values that result after 24 hours since a previous critical has been called for the same admission.
  - Currently the laboratory only calls the first critical troponin for any patient admission.
  - Calling a second critical after 24 hours could provide advanced notice for cases that may be transferred to other health care teams and/or if re-infarction should occur.

Regulatory requirements from the College of American Pathologists (CAP) require laboratories to notify providers of values that are deemed critical (potentially needing immediate action). The laboratory medical director, in conjunction with medical staff, usually determine which analytes will be designated as critical, and which levels will be considered critically high and/or critically low.

It is required that the laboratory notify the provider of each critical value within 60 minutes of the result. One issue that Pathology is working to address, in addition to the modifications discussed above, is to decrease delays in communicating (calling) critical values. We are annotating incidences, and most of the reasons appear to be related to failure to reach staff who can accept the value. Pathology will work with receiving locations to address this issue after enough data is collected to potentially identify root-causes.

The art and science of identifying and effectively communicating “highly pathological” values plays a critical part in total laboratory quality. Transmission of critical laboratory values is also included among the list of quality indicators developed by the Working Group on Laboratory Errors and Patient Safety (WGLEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)¹. The determination of alert thresholds then remains a challenge; however, we believe that the changes described above will improve the overall quality and services of our pathology department.

Reference:


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**Laboratory quality topic 3 of 3: Delta checks:**

Delta checks are an entity in the laboratory this is almost completely transparent to providers and patients. Recently our delta check policy and analyte lists were evaluated. For reasons described below, this evaluation resulted in changes that may not be realized by providers or patients. However, the delta checks are a critical part of total laboratory quality clinical management.

In the clinical laboratory, delta checks measure of the difference between sequential results from the same patient. Sometimes, potential errors can be identified when there is a significant interval change in results. The problem may be associated with the previous or the current specimen. When identified, delta checks can initiate an investigation before results are reported.

**Salient features of Delta Checks:**

- Delta checks, while usually unknown to providers, are ubiquitously used in clinical laboratories as a patient-based quality assessment tool.
- Delta checks support auto-verification procedures that promote laboratory efficiency.
- The delta check quality tool is designed to detect potential errors associated with processes that include specimen collection, analysis, or reporting problems.
- As a quality tool, delta checks serve as back-up safety for identifying testing errors that
might otherwise not be detected and could therefore lead to a compromise in total labora-

tory quality and compromise in patient care.

The laboratory director has the responsibility of selecting the most appropriate set of delta checks.
Analytical, technical, physiological, and clinical processes must be considered when deciding on the delta check menu and rules will be implemented in the laboratory. A limited group of analytes with minimal physiological variation are usually selected. This will limit the number of unwarranted alerts/flags. It is also wise to limit delta checks to analytes that are frequently ordered on the same patient during a short time period. Because of these delta check qualities, they are principally confined to hospital where patients are repeatedly tested. Appropriate delta check selection and criteria should be balanced to avoid delays in reporting in conjunction with the knowledge that many are not associated with an identified error.

Delta checks are best identified through programming into the laboratory information computer system. For example, mean corpuscle volume (MCV) may be considered a good analyte for a delta check in hematology. A MCV delta check would compare a patient’s current value of 80-fL to their last value obtained 12-hours ago, which was resulted as 95-fL. This change could reflect a pathological process or a testing issue. The laboratory personnel would be responsible to determine if an error occurred before reporting the result or contacting the provider. Glucose is an example of an analyte that may not be included in the delta check menu due to expected variations during short periods of time.

When reviewing the previous delta check menu, we identified several important and practical considerations to improve the quality in our laboratory.

- We have sought out to identify an appropriate number of different analytes and testing time-points to maximize the use of delta checks at our TTHUSC/UMC laboratory.
- We have incorporated the use of documented and standardized methodology for investigating delta check alerts and customized them by analyte.

- Such improvements serve to increase the number of problems detected while streamlining the evaluation process.

We will continue to monitor the use of our delta checks so that it remains consistent with best laboratory practices and optimization of our provider and patient needs.

Reference:


Please contact Dr. Jude Abadie in the department of pathology at jude.abadie@ttuhsc.edu or 915-215-4956 with question related to body fluids, critical values, delta checks, or other question related to pathology testing.

IIIB. Transfusion Medicine/Coagulation News

Should Low-Titer Group O Whole Blood be used for Transfusion Therapy in Pediatric Trauma Patients?

Bradford Ray, RABT, PBMT, BC

Early treatment of traumatic hemorrhagic shock (THS) in all patients is crucial to patient survival for a variety of reasons, including [1]:

- High 30-day morbidity and mortality rates (adults, 20% to 25%; children, ~50%).
- THS is the most common cause of:
  - Death in patients 1 year to 49 years of age
  - Years of life lost for patients < 75 years old
  - Preventable deaths, accounting for ~30,000 deaths/y in the US
- Death within 1-3 hours (mean = 1.6 h) post-injury and within 30 min in severe THS

Optimal methods for early treatment of THS were pioneered by the US military during the wars in Iraq (Operation Iraqi Freedom, Mar 2003 – Nov 2011) and Afghanistan (Operation Enduring Freedom, Oct 2001 – Dec 2011), including
the use of cold-stored, low-titer (i.e., anti-A and anti-B antibody titers < 1:256) Group O whole blood (LTOWB) for prehospital THS. LTOWB contains group O red blood cells and plasma containing low levels of antibodies (i.e., making it safe for transfusion in patients of all blood types.

In the past decade, US military emergency medical centers have changed the treatment of prehospital resuscitation from the use of crystalloids/colloids to whole blood products such as LTOWB. When the Department of Defense analyzed the data from 543 pediatric trauma patients with penetrating injuries that occurred in either Iraq or Afghanistan, 23 received LTOWB and 18 met the definition of a mass transfusion. There results indicated: “Survival is no worse when using LTOWB,” and when adjusted for additional factors, “Whole blood was associated with higher survival rates” [2].

In 2018, the American Association of Blood Banks (AABB) approved the use of LTOWB for massively bleeding patients of unknown ABO type. More recently, several published studies (see Ref. [1]), provided substantial evidence on the advantages of LTOWB over conventional treatment of prehospital hemorrhagic shock using crystalloids.

The advantages of cold-stored LTOWB over crystalloids/colloids for treatment of pre-hospital hemorrhagic shock include [1]:

- More concentrated than conventional, individual blood component therapy.
- Cold-stored platelets support hemostasis better than room temperature-stored platelets.
- Logistical benefits of transporting, storing, and transfusing of one blood product instead of three separate blood components.
- Less exposure to potential pathogenic and non-pathogenic agents that might affect treatment outcomes.
- Higher survival rates.

Despite these advantages, the use of crystalloids, red blood cells, plasma, and/or platelets currently remains the principal approach in the resuscitation of severely bleeding patients. However, as the weight of the evidence in support of LTOWB over crystalloids continues to mount, it begs the question, posed by Spinella et al. [1]: “Should we stock emergency transport vehicles (ambulances and helicopters) with red cells, plasma, and platelets or should we use LTOWB instead” (and, presumably, in the treatment of both adults and children with THS)?

The high 30-day mortality rate for children requires early (pre-hospital) and effective treatment of pediatric trauma patients. A 2018 Survey of hospitals using LTOWB in the treatment of THS asked: “Do you use LTOWB for pediatric trauma? Among the 16 hospitals that responded to this Survey question, only 2 responded “Yes” and 14 responded “No.” The two hospitals (and the age range for LTOWB use in their pediatric patients) that responded “Yes” were the University of Pittsburgh (age 2 and above) and the University of Texas San Antonio (age 5 and above) [3].

In addition, a meta-analysis of whole blood transfusion versus component therapy in trauma resuscitation patients yielded 1759 reference citations of which 12 studies (7 from the civilian setting; 5 from the military setting) met the inclusion criteria for systematic review [4]. A total of 8431 patients, including patients with blunt force and/or penetrating injury trauma, were among the patients comprising these 12 studies. The principal finding from this study was: “…compared with conventional component transfusion, whole blood was not associated with 24-hour or in-hospital mortality.”

Although there is less debate over the benefits of WB or LTOWB over conventional therapy for treatment of THS in adult patients, there is limited evidence on their use in transfusion therapy and mass transfusion protocols (MTPs) in pediatric trauma patients. In what is perhaps the first literature review of this topic, Nystrup et al. [5] reported that “…only a few small descriptive studies and case reports have investigated the use of predefined MTP in pediatric trauma patients.” Further, these authors suggested that immediate identification and implementation of “viscoelastic hemostatic assay (VHA)-directed treatment of traumatic coagulopathy could ensure faster hemostasis and thereby, potentially, reduce bleeding as well as the total transfusion requirements and further improve outcomes in pediatric trauma patients.” VHA's include: thromboelastography (TEG), rotational thromboelastometry (ROTEM), Hemosonics Quantra, and Sonoclot.

More recently, Crowe et al. [4] suggested that future studies to evaluate whole blood use in the
treatment of civilian trauma might include endpoints, other than just hospital mortality, such as early mortality or physiologic measures such as ROTEM.

Based on the evidence above, it appears that the use of WB or LTOWB in the treatment of pediatric trauma patients is not yet ready for prime time. UMC El Paso is currently not using WB in the treatment of pediatric trauma patients and follows the transfusion guidelines from the University of New Mexico Albuquerque: https://emed.unm.edu/common/documents/pediatric-massive-transfusion-procedure-information.pdf).

References
2. Fisher A. Whole blood may be viable treatment option for pediatric trauma patients, http://blog.aabb.org/whole-blood-may-be-viable-treatment-option-for-pediatric-trauma-patients/

For more info contact: Bradford Ray | 915 996-5503

A final note from the editor of Path-O-Gram
Dr. Jude Abadie

Since joining the TTUHSC-UMC family in July 2020, I have been fortunate to be a part of an exceptionally strong team of laboratorians in the pathology department. Our team’s strength can be appreciated at every level of leadership throughout pathology. During continuous challenges from COVID-19, our pathology family has demonstrated a remarkable ability to foster outstanding work ethics while providing the highest quality of services for our providers as we continue to deliver superior patient care.

Through many COVID-related professional and personal challenges, our office-management group has maintained seamless support for departmental meetings, continuing-education activities, and essential day-to-day operations. Clinical sections of our laboratory, such as microbiology-immunology, have tirelessly and seamlessly supported COVID testing needs while continuing to meet all other mission requirements.

Furthermore, our chemistry, hematology, cytology, point-of-care testing, and laboratory information technology sections are uniformly exceptional in providing pathology services within our department, throughout the hospital system, and at our remote El Paso clinic locations. I have complete trust in our techs and laboratory operations. From my interactions with our laboratory team during the past 4 months, I know they treat all patient samples as if those samples were from one of their own family members.

The aforementioned strengths of our pathology department are tightly woven with leadership from our chief Dr. Orazi, our vice chair Dr. Hakim, and our pathologists. I am honored to work and serve with such a strong, caring, formidable group of professionals. I believe that the challenges we currently face will make our pathology department grow on personal and professional levels in the medical service of El Paso and surrounding communities.

I’m proud to call our team of laboratorians (management, techs, and pathologists) part of my professional family, and I’m grateful for their dedication to patient care. I look forward to the future with great anticipation for opportunities to support our pathology educational and clinical services.