

From the Mind of the Chair

Greetings PMF Colleagues and Happy 2026!



Welcome to the first newsletter of the new year. I hope you are all doing well during these winter months. For those of us in the United States, many just endured a historic winter storm that brought heavy snow, ice, and widespread power outages. The town from which I am

writing is only now beginning to thaw out after one of the worst ice storms in its history; thankfully with heat and power so I can write this portion of our newsletter.

The “wintering” effect is real it offers a wonderful opportunity for reflection. I am fortunate to highlight several key accomplishments from the past year. In 2025, the Pediatric and Maternal Fetal Medicine (PMF) Division enjoyed the spotlight in meaningful ways, and it continues to inspire me to see these efforts reinforcing the ADLM mission—better health for all through laboratory medicine.

Our members were actively involved in numerous initiatives, sometimes too many to count! We hosted well-attended webinars on topics such as urine drug screening, eGFR equations in pediatrics, and one co-hosted with the American College of Medical Genetics. Other impactful work included our grassroots campaign with ADLM on children’s health and overall access to laboratory testing. PMF Chair-Elect Dr. Amy Pyle-Eilola shared a heartfelt [video](#) message about pediatric reference intervals (PRIs). Treasurer Dr. Erin Schuler was also featured in an interview with ADLM

President Dr. Paul Jannetto on [Episode 39 of Laborastories: The Podcast](#). Finally, Past Chair Dr. Stan Lo, along with Drs. Dietzen and Tacker, delivered a successful congressional briefing on newborn screening, PRIs, pediatric laboratory-developed tests, and related advocacy. ADLM encouraged all members to reach out to their state and federal representatives. If you missed the opportunity to send a letter, the link is available [here](#).

As we enter this new year, let us take pride in our collective achievements and recommit to advancing PMF care. Here’s to a year of growth, innovation, and shared success. Happy New Year to all!

Please also enjoy this newsletter, which features two main articles: “The ABC’s of Pediatric Laboratory Medicine: Interferon Insights: IGRA Testing in Pediatric and Maternal-Fetal Care” and “Continuous Glucose Monitoring in Pediatric Inpatient Care: Current Evidence and Future Directions.” In addition, there is a fabulous interview with Dr. Sridevi Devaraj, where she provides many words of wisdom. Of course, and lastly, if you have any questions, ideas, or comments about the PMF Division, please feel free to contact me.

Sincerely,

Joe Wiencek, PhD, D(ABCC), FADLM
Chair, Pediatric and Maternal Fetal Medicine

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The ABC's of Pediatric Laboratory Medicine:

Q is for QuantiFERON-TB



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Interferon Insights: IGRA Testing in Pediatric and Maternal-Fetal Care

Prior to the COVID-19 pandemic, *Mycobacterium tuberculosis*, the causative agent of tuberculosis (TB), was the leading cause of death from a single infectious agent worldwide according to the World Health Organization (WHO). During the pandemic, disruptions to public health infrastructure, laboratory capacity, and routine medical care resulted in an estimated 20–25% decline in TB case notifications across many jurisdictions (1, 2). Importantly, this decline did not reflect a true reduction in TB incidence, but rather a reduction in reporting and diagnosis of cases. In the United States, TB incidence rose markedly in 2022 among children ≤ 4 years of age (28.8%) and adolescents and young adults aged 15–24 years (24%) compared with 2021, approaching rates observed prior to the pandemic (2). The consequences of these missed diagnoses are becoming increasingly apparent. Despite availability of effective diagnostic tools and curative antimicrobial therapy, TB persists due to structural inequities, delayed diagnosis, and limited access to care. The downstream consequences of missed or delayed TB diagnoses are still unfolding, including increased community transmission and more advanced disease at presentation (3).

TB infection versus TB disease

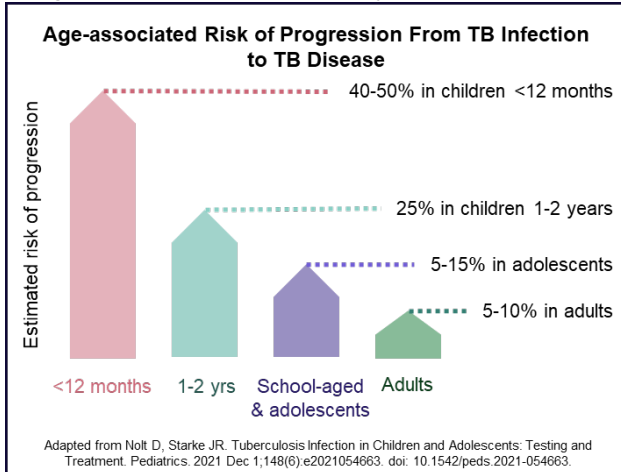
A core concept in TB management is the distinction between TB infection and TB disease. TB infection (TBI), previously termed latent TB infection (LTBI), is defined by immunologic evidence of exposure to *M. tuberculosis* in asymptomatic individuals with normal chest imaging who test positive on TB-specific assays such as the tuberculin skin test (TST) or interferon-gamma release assay (IGRA). In contrast, TB disease reflects active replication of the bacterium with corresponding clinical manifestations and, in most cases, radiographic or microbiologic evidence. Transmission of *M. tuberculosis* occurs only from individuals with active TB disease, as latent TB infection is not contagious.

Risk factors for acquiring TB infection and/or progression to active TB disease include close contact with individuals with confirmed or suspected contagious TB; clinical or radiographic findings suggestive of TB; immigration from or significant travel to TB-endemic regions with substantial local exposure; HIV infection; and underlying medical conditions such as diabetes mellitus, chronic renal failure, malnutrition, congenital or acquired immunodeficiencies, or treatment with TNF- α antagonists.

Age-associated risk of progression from TB infection to disease in children

Accurate diagnosis of TB infection and active disease is particularly important in pediatric populations. Children frequently exhibit nonspecific symptoms, microbiologic confirmation can be difficult due to paucibacillary disease and challenges in obtaining diagnostic specimens, and immunologic tests have significant limitations in this age group (2). In the general population, the lifetime risk of progression from TB infection to active TB disease is approximately 10%. However, this risk is not evenly distributed across age groups due to immature immune states in children (4).

Risk of progression to TB disease declines with increasing age. Infants younger than 12 months have an estimated 40–50% risk of developing TB disease following infection if untreated. Children aged 1–2 years also have an elevated risk of progression of approximately 25%, and school-



aged children and adolescents generally demonstrating even lower progression rates at 5-15%. Adults typically have the lowest risk unless additional factors, such as immunosuppression, are present. These age-associated differences underscore why early identification of TB infection in children is not merely a preventive measure, but a critical intervention to avert severe disease, including disseminated TB and TB meningitis, conditions that disproportionately affect young children and carry high morbidity and mortality.

Interferon-Gamma Release Assays (IGRA) as a screening tool for TB Infection

There is no gold standard diagnostic test for the detection of TBI or LTBI. The two primary immunologic methods for detection of TBI are TST and IGRAs. IGRAs are blood-based tests that measure interferon-gamma (IFN- γ) production from sensitized T-cells using *M. tuberculosis*-specific antigens, whereas the TST involves intradermal injection of purified protein derivative (PPD), a heterogeneous antigen mixture that may cross-react with nontuberculous mycobacteria. Unlike TST, IGRAs demonstrate higher sensitivity for detecting TB infection in immunosuppressed individuals and yield fewer false-positive results due to cross-reactivity with the Bacille Calmette-

Guérin (BCG) vaccine and most nontuberculous mycobacteria, with the notable exceptions of *M. kansasii*, *M. marinum*, *M. szulgai*, *M. leprae* (5).

From a practical standpoint, IGRAs offer several logistical advantages. They require a single blood draw, provide objective laboratory-based results, and eliminate the need for a return visit to interpret test findings, as is required for TST induration measurement. These features make IGRAs an attractive option for TBI screening in many clinical settings. However, blood collection may be challenging in young children, particularly infants and toddlers, and pre-analytical variables can influence test performance including volume, hemolysis, and delays or temperature deviations during transport that reduce T-cell viability.

Historically, WHO-recognized IGRAs included T-SPOT (Oxford Immunotec), QuantiFERON-TB Gold Plus (QIAGEN), and TB-IGRA (Wanta Biopharm); in 2025, the WHO additionally endorsed STANDARD E TB-Feron ELISA (SD Biosensor) and LIAISON® QFT-PLUS (QIAGEN/Diasorin) for TBI testing (6). Since the first FDA-approved IGRA (QuantiFERON-TB) became available in 2001, its use in pediatric populations was initially limited due to concerns regarding lower sensitivity in immunocompromised children and in those under 2 years of age with immature immune systems, which sometimes led to indeterminate results.

More recently, however, accumulating evidence has supported similar diagnostic performance when compared to TST. Additionally, newer iterations of the QuantiFERon assay have improved both feasibility and sensitivity. The QuantiFERON-TB Gold In-Tube (QFT-GIT) assay, introduced in 2007, enabled remote blood collection via pre-coated tubes. The current generation, QuantiFERON-TB Gold Plus, includes separate antigen tubes designed to stimulate both CD4⁺ and CD8⁺ T-cell responses, enhancing sensitivity for TBI screening compared with CD4⁺ T-cell stimulation alone. In a study conducted by the Centers for Disease Control and Prevention (CDC) comparing TST and IGRAs in asymptomatic, foreign-born

children, the positive predictive value (PPV) for TST was 10% in children under 5 years, compared with 70–73% for IGRAs. In children over 5 years, the PPV was 60% for TST and 98–99% for IGRAs. This higher specificity is particularly advantageous in BCG-vaccinated populations, where TST specificity may be reduced to 60–80% due to vaccine-related cross-reactivity, whereas IGRA specificity remains largely unaffected. In non-BCG-vaccinated pediatric population, the sensitivity of IGRAs and TST are relatively similar and range 80–90% (4). Emerging data also indicate that in children under 2 years of age, IGRAs demonstrate sensitivity comparable to TST, supporting their use even in this youngest age group in areas of low and high TB incidence (7, 8).

Despite growing evidence supporting IGRA use in young children, guideline recommendations remain inconsistent across major governing bodies. In 2024, the American Academy of Pediatrics (AAP) updated its guidance to recommend IGRA-based screening for at-risk children of all ages, representing a shift from earlier recommendations that limited IGRA use to children aged ≥ 5 years (9). This change was supported by studies demonstrating non-inferiority of IGRAs compared with TST for diagnosing TB infection in pediatric populations under 5 years of age (7–9). In contrast, CDC (2017) and WHO (2025) guidance remains more conservative. The CDC continues to recommend TST over IGRA for children ≤ 5 years of age, while WHO recommends TST as the preferred test for children aged 6 months to 2 years. These recommendations reflect concerns over limited data in very young children and practical challenges related to blood collection and availability of IGRAs globally (5, 6).

Overall, IGRAs offer notable advantages but also have important limitations in pediatric populations. The greater sensitivity and specificity of IGRAs are typically observed in areas with high vaccination rates. In areas of low incidence, IGRAs and TST are comparable in most cases. Indeterminate or borderline results may also occur with IGRAs, especially in very young children and immunocompromised

patients. Clinicians should recognize that, like the TST, IGRAs cannot differentiate latent TB infection from active TB disease, and neither test reliably predicts progression from infection to disease. Consequently, both IGRAs and TST should be interpreted in the context of risk assessment, radiographic and microbiologic findings, and overall clinical judgment.

Considerations for TBI screening during pregnancy

Pregnancy presents unique considerations for TBI screening and diagnosis, as physiologic immune modulation may affect test performance, and concerns regarding fetal safety often influence clinical decision-making (10). Untreated active TB disease during pregnancy is associated with adverse maternal and neonatal outcomes, including miscarriage, preterm birth, and low birth weight. Although congenital TB is rare, with fewer than 500 cases reported globally, it carries a high mortality rate of up to 50%, highlighting the importance of timely identification of maternal infection.

Early detection enables risk stratification and planning of antimicrobial therapy, particularly in individuals with recent exposure within 2 years, who are at higher risk for progression to active disease. In many cases, antimicrobial treatment can be deferred until 2–3 months postpartum. Both TST and IGRAs are considered safe for use during pregnancy and are used in evaluation of TB during pregnancy (10), though a meta-analysis of TST and IGRA testing in pregnant women demonstrated a concordance of 49.4%–96.3% (11).

Summary

In the aftermath of COVID-19–related disruptions to TB care, effective screening remains essential, particularly for pediatric and pregnant populations at increased risk of adverse outcomes. IGRAs offer practical and higher predictive value in selected populations, but their limitations and variability across guidelines require careful, context-specific use. Integrating IGRA and TST results into a comprehensive clinical assessment is essential

to support timely identification, appropriate management, and prevention of TB disease progression.

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Excerpts from the Literature



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Continuous Glucose Monitoring in Pediatric Inpatient Care: Current Evidence and Future Directions

Continuous glucose monitoring (CGM) has transformed diabetes management over the past two decades by enabling real-time minimally invasive assessment of interstitial glucose concentrations. CGM has become part of the standard of care for many individuals with type 1 diabetes (T1D), especially with the integration of the automated insulin delivery system. Its use is endorsed by major professional organizations, including the International Society for Pediatric and Adolescent Diabetes (ISPAD), the American Diabetes Association (ADA), and the European Association for the Study of Diabetes (EASD) (1). Despite the well-recognized benefits, CGM devices remain FDA-cleared only for outpatient

use. Their introduction into inpatient settings was largely accelerated during the COVID-19 pandemic, when the FDA issued temporary enforcement discretion that allowed hospitals to use CGMs to reduce healthcare worker exposure and preserve personal protective equipment (1, 2).

Numerous studies have validated the accuracy and clinical utility of CGM in adult inpatient populations but the evidence supporting their use in hospitalized pediatric patients remains limited (1, 2). Recent pediatric studies have begun to address this gap. Randomized controlled trials such as the REACT study demonstrated that CGM-guided management improved time in range and reduced exposure to prolonged and severe hypo- and hyperglycemia without increasing skin complications in preterm infants requiring intensive care. These findings suggest that CGM may serve as a valuable adjunct to traditional neonatal glucose monitoring, although accuracy was not consistently assessed as a primary outcome (3). In older pediatric populations, several studies have examined CGM performance in critically ill and diabetic ketoacidosis (DKA) patients. Retrospective and prospective investigations using Dexcom G6 devices found that most CGM readings fell within clinically acceptable Clarke Error Grid zones A and B. However, as in adult populations, accuracy declined during hypoglycemia. In DKA, additional limitations included sensor warm-up delays and an upper measurement ceiling near 400 mg/dL, which reduced CGM utility for patients with severe hyperglycemia (1).

Overall, early pediatric studies suggest generally acceptable CGM performance but have been constrained by small sample sizes, narrow clinical settings, and incomplete representation of hypoglycemic and hyperglycemic events—precisely the ranges in which accurate data are most critical for clinical decision-making (1). One of the larger analyses reported a mean absolute relative difference (MARD) of 15.9% across 202 type 1 diabetes pediatric patients, but few paired hypoglycemic measurements were available, limiting conclusions in clinically critical ranges (4). This gap is significant because consensus

guidelines recommend confirmatory testing of CGM-detected hypo- and hyperglycemia using conventional glucose methods before treatment decisions are made. Yet, until recently, adherence to these recommendations in pediatric inpatient care had not been systematically evaluated.

The most comprehensive assessment of pediatric inpatient CGM performance to date was conducted by Farnsworth et al (5). This retrospective study analyzed 2,228 paired CGM and standard-of-care (SOC) laboratory or point-of-care (POC) glucose measurements from 72 hospitalized children with diverse causes of dysglycemia. The overall CGM MARD was 14.8%, with 99.2% of readings falling within clinically acceptable Parkes Error Grid zones A and B. However, accuracy declined substantially at glucose extremes, with the MARD exceeding 20% during hypoglycemia (<70 mg/dL) and remaining elevated in the hyperglycemic range (>180 mg/dL). By comparison, POC glucose meters showed stronger agreement with laboratory reference testing, with a MARD of 8.5%.

Farnsworth et al. also evaluated adherence to institutional policies requiring confirmatory testing of abnormal CGM values. Despite these requirements, only 80.2% of hypoglycemic and 16.5% of hyperglycemic CGM readings were verified with POC testing within 30 minutes. Concordance between CGM- and POC-based glycemic classification was moderate ($\kappa = 0.66$), indicating substantial discordance near clinical decision thresholds. These findings underscore that, while CGM provides valuable real-time trend information, it is not yet sufficiently reliable as a standalone diagnostic tool for hypoglycemia or hyperglycemia in hospitalized pediatric patients (5).

Collectively, the existing literature indicates that, while CGM holds substantial promise for inpatient pediatric glucose monitoring, important limitations remain—particularly regarding accuracy at critical glucose thresholds and inconsistent confirmatory testing practices. Recent large-scale pediatric evaluations have strengthened the evidence that CGMs achieve

accuracy comparable to outpatient performance. However, these studies also reaffirm the indispensable role of SOC methods for verifying extreme CGM readings (5).

The future of pediatric inpatient CGM will hinge on both technological innovation and thoughtful clinical implementation. Improvements in sensor precision, standardized hospital protocols, rigorous validation studies, staff education, and seamless integration into electronic medical records will be critical for safe and effective adoption. As hospital-based CGM adoption increases, particularly among pediatric populations with diverse etiologies of dysglycemia, additional multicenter studies are needed to evaluate patient safety, clinical outcomes, and adherence to confirmatory testing guidelines (1, 5).

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Interview with a Distinguished Colleague: 2025 Award for Outstanding Contributions to Pediatric and Maternal-fetal Clinical Chemistry

By Joe Wiencek, PhD

Sridevi Devaraj, PhD, DABCC, FADLM, FRC

Medical Director, Clinical Chemistry, Clinical Biochemical Genetics and Point of Care, Texas Children's Hospital and Professor of Pathology & Immunology, Baylor College of Medicine, Houston TX



Dr. Devaraj, you've mentored countless trainees and early-career professionals throughout your career. Can you share some principles you prioritize in mentorship?

First, I believe mentors can only become effective mentors because of their mentees. In my view, mentorship is about helping each individual realize their unique potential, and the latter may be different for each mentee. One of the main principles I prioritize in mentorship would be that- I try my level best to lead by

example. I hope to model the values that I would like to be nurtured in them—curiosity, humility, resilience, hard work and being ethical and compassionate.

Secondly, I try to instill as much confidence in them by real-world experiences and providing them with not only the training in the work they need, but exposure to all facets of my clinical chemistry life but also explaining to them that when we share knowledge, it grows and we grow with it. I also feel that by the end of their training, the mentees and early career professionals need to be empowered to take ownership of their work, and I am very delighted when they see every data point, every experience in the lab or using lab data, that is yet another story that is waiting to be understood.

Among your extensive body of work in pediatric laboratory medicine, which research project are you most proud of, and how has it directly improved pediatric diagnostic care?

This is an especially hard question to answer. To me every research question is important and if it is not impactful, why do it, why publish it? Translating analytical data into clinical impact and where it changes a patient's care or outcome gives meaning to all the research we do in the lab. Briefly, of the past few publications, an area I hold close is our biomarker research in acute kidney injury (AKI), which has advanced early detection and informed clinical decision-making in critically ill children. Another project I'm very proud of is our work improving gestational diabetes testing and postpartum follow-up. We identified significant gaps in how women were screened and monitored after delivery, which often led to missed opportunities to prevent type 2 diabetes later in life. By improving test protocols and helping establish better post-delivery follow-up pathways, we've

been able to support healthier outcomes for both mothers and their babies. And then there's our work on Amnisure testing in preterm labor. That's a project that really combined analytical validation with clinical impact. By improving diagnostic accuracy for premature rupture of membranes, we helped clinicians make faster, more confident decisions in cases where every hour can affect neonatal outcomes. More recently we are working on improving pediatric lipid screening and the validation of new LDL-C equations which I believe will define how clinicians assess cardiovascular risk in children, providing more accurate tools for early intervention, especially in those with familial hypercholesterolemia.

What has sustained your passion and effectiveness in laboratory medicine over your career and what advice would you give to others aiming for similar path?

What sustains me is the unique sense of purpose that laboratory medicine offers—every test we validate, every protocol we optimize, directly affects a patient's life. That connection never loses its power. I am also very thirsty for new things, new knowledge and draw immense energy from continuous learning and collaborating with our physician colleagues. Every day is a new and exciting day. Every day comes with its unique sets of challenges and wins. Science is evolving so rapidly that curiosity itself becomes a renewable resource. Seeing the world sometimes from the eyes of our physician colleagues in other divisions is so revealing and I believe, mutually beneficial. My advice- We must always keep the larger picture in sight and stay grounded on the reason we actually entered the field. Never shirk hard work, always stay curious, think out of the box and share your solutions, communication is key, humility is key and compassion is key. My view—we are the best

clinical scientists who have the capacity to bridge the analytical with the human.

As someone who has witnessed the evolution of our field, how do you see current emerging technologies reshaping the field in the next 10 years, and what role should today's leaders play in preparing for that future?

Now, you make me feel old. But let me answer the question, I think for a long time our science was largely reactive testing rather than predictive and preventive diagnostics. Emerging technologies like AI-driven diagnostics, using

machine learning tools, point of care molecular testing and the advent of mass spectrometry derived data integrated into multi-omics will pave the future. But we also need to be careful and engage in ethical, equitable and accurate laboratory medicine. We should be the leaders in making sure that innovation doesn't outpace quality, and that technology improves access to health for all patients, especially those that are underserved or specialized populations. We should also groom the next generation to think critically about data, understand the limitations of algorithms, and never lose sight that behind every lab result, is a vulnerable human being.

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