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WeQas

GLOBAL PROVIDER OF QUALITY
IN DIAGNOSTIC MEDICINE



EXTERNAL
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REFERENCE
MEASUREMENT
SERVICES



EDUCATION &
TRAINING

Future Developments

Gareth Davies

Overview

- Bone Markers
- POCT Strep A
- PAMG-1
- Traumatic Brain Injury
- Genedrive
- Faecal Calprotectin
- Future Possibilities

Bone Markers

- Bone turnover markers (BTMs) are biochemical products of bone metabolism that reflect the rate of bone remodelling.
- BTMs provide insights into skeletal metabolism for diagnosis and management of osteoporosis, Paget's disease, and renal osteodystrophy.
- Enable monitoring of treatment response to anti-resorptive therapies (bisphosphonates, denosumab) and anabolic agents (teriparatide, abaloparatide).
- P1NP (released during collagen synthesis by osteoblasts) and CTX (generated during collagen degradation by osteoclasts) are designated by IOF/IFCC as reference markers for formation and resorption respectively.
- **Markers Included in Programme**
- **P1NP:** Preferred formation marker with low biological variability, room temperature stability, minimal circadian variation.
- **CTX:** Preferred resorption marker with rapid response to anti-resorptive therapy. Significant circadian variation requires standardised collection.
- **NTX:** Alternative resorption marker (serum and urine). Urine NTX normalised to creatinine.
- **BAP:** Alternative formation marker. Useful for Paget's disease and chronic kidney disease.
- **Vitamin D & PTH:** Assessment of calcium homeostasis and secondary hyperparathyroidism

POCT Strep A

- In most patients, sore throat is a self-limiting, viral condition that resolves within a week.
- However, in some patients, sore throat is caused by a bacterial infection, most commonly Streptococcus A.
- In rare cases, complications such as rheumatic fever, post-streptococcal glomerulonephritis or sepsis can occur.
- Identification of patients with bacterial infection can direct the use of antibiotics, ensuring patients receive appropriate treatment, whilst avoiding contributing to antibiotic resistance.
- Several POCT devices for rapid qualitative identification of Streptococcus A bacteria in throat swab samples are widely available, with faster turnaround time than laboratory culture.
- The most common methods are rapid antigen detection tests, which rely on visual inspection of test strips, although newer methods utilising isothermal nucleic amplification technology are also in use.



POCT Strep A

- Programme started October 2025
- Frequency: Monthly
- Samples: 3 * 1.0 mL
- Material: Buffered material spiked with inactivated Streptococcus A
- Key Features:
 - Stable liquid samples supplied ready to use (no pre-analytical preparation required)
 - Suitable for both Rapid antigen detection tests and Nucleic Acid detection devices
 - Wide range of bacterial loads covered.

PAMG-1

- **Pre-Term Labour Marker**
- Preterm labour is defined as regular contractions of the uterus resulting in changes in the cervix that start before 37 weeks of pregnancy.
- Point of care (POC) biomarker tests are intended for use with other clinical information to assess the risk of preterm birth in women with symptoms of preterm labour who have intact amniotic membranes.
- Placental alpha microglobulin-1 (PAMG-1) is a protein released from the lining of the uterus into the amniotic cavity throughout pregnancy.
- It is found in very high concentrations in amniotic fluid and in very low concentrations in normal vaginal discharge.
- Studies have demonstrated a strong correlation between the presence of PAMG-1 in cervicovaginal discharge and imminent delivery.
- PartoSure is a qualitative lateral flow, immunochromatographic POC test designed to detect (PAMG-1) in vaginal secretions during pregnancy. The test has a limit of detection of 1 ng/ml and a measuring range of 1 to 40,000 ng/ml.

PAMG-1

- **Premature rupture of the membranes (PROM)**
- Premature rupture of the membranes (PROM) at term occurs in 5 to 10% of pregnancies and pre-term PROM (PROM<37 weeks' gestation) occurs in approximately a third of all premature births and is associated with significant neonatal morbidity and mortality.
- Without clear evidence of amniotic fluid loss observed by speculum examination, the diagnosis of PROM can be uncertain and complementary diagnostic tests are recommended [NG25]
- insulin-like growth factor binding protein-1 (IGFBP-1 - Actim® PROM) and placental alpha microglobulin-1 (PAMG-1 - AmniSure®).
- NICE guideline [NG25] Preterm labour and birth (last updated June 2022).
- **1.3 Diagnosing preterm prelabour rupture of membranes (P-PROM)**
- if pooling of amniotic fluid is not observed, perform an IGFBP-1 or PAMG-1 test of vaginal fluid.
- 1.3.2 If the result of the test is positive, do not use the test results alone to decide what care to offer the woman, but also take into account her clinical condition, medical and pregnancy history and gestational age, and either: offer care consistent with the woman having P PROM or re-evaluate later
- 1.3.3 If the results of the IGFBP-1 or PAMG-1 test is negative and no amniotic fluid is observed:
 - do not offer antenatal prophylactic antibiotics, explain to the woman that it is unlikely she has P- PROM, but that she should return for reassessment if there are any further symptoms suggestive of P- PROM or preterm labour.

PAMG-1

- First distribution to be sent December 2025
- Frequency: Monthly
- Samples: 2 * 0.5 mL
- Material: The base material is a saline solution to be mixed with a blinded amount of lyophilised PAMG-1 protein purified from human amniotic fluid or lyophilised sucrose (negative)
- Key Features:
 - Samples stable at room temperature before reconstitution
 - Suitable for PartoSure and AmniSure tests
 - Programme will assess both site and device performance

Traumatic Brain Injury Markers

- TBI occurs when an external force injures the brain (e.g., falls, sports injuries, vehicle accidents).
- Can range from mild (concussion) to severe, leading to cognitive, physical, or emotional impairment.
- Mild TBI (mTBI) often has subtle symptoms but may still involve structural brain damage not obvious on initial exam.
- Blood Biomarkers in TBI
 - GFAP (Glial Fibrillary Acidic Protein): Released by glial cells when the brain's supportive tissue is damaged.
 - UCH-L1 (Ubiquitin C-terminal Hydrolase L1): Released from neurons after injury.
- Measuring these proteins in blood provides objective evidence of brain injury, complementing clinical assessment – can help determine which patients may safely avoid CT imaging and which require further evaluation

Genedrive

MT-RNR1

- In cases of suspected Sepsis, antibiotic treatment must be administered within 1 hour of admission to the unit (NICE Guidelines).
- Gentamicin (aminoglycoside antibiotic) is the first line of treatment for newborn babies who are suspected to be at risk of sepsis caused by bacteria (NICE guidelines 2021).
- Aminoglycoside antibiotics are used, because they are a low cost, broad-spectrum antibiotic with fewer resistant strains.
- Individuals with the m.1555G gene variant on the mitochondrial gene MT-RNR1 are highly susceptible to irreversible, bilateral hearing loss, when given aminoglycoside antibiotics
- Population-based studies estimate that 1:500 people have this variant.



Genedrive

CYP2C19

- The CYP2C19 gene encodes a liver enzyme of the same name that is responsible for metabolizing many clinically relevant drugs, including antidepressants, proton pump inhibitors, and the antiplatelet clopidogrel.
- Clopidogrel is an antiplatelet treatment for secondary prevention of minor strokes and transient ischaemic attack (TIA), also known as a mini stroke.
- DNA variants in the CYP2C19 gene can result in variable levels of enzymatic activity ranging from poor metabolism to ultra-rapid metabolism.
- Patients given clopidogrel who are poor, or intermediate metabolisers experience worse outcomes including reduced platelet inhibition and increased risk for major adverse cardiovascular and cerebrovascular events.

Faecal Calprotectin

- Faecal Calprotectin is a protein biomarker released during intestinal inflammation, particularly associated with inflammatory bowel disease (IBD)(Crohn's, Ulcerative colitis)
- In diseases with no inflammation e.g. irritable bowel syndrome (IBS) faecal calprotectin will be normal
- Differentiates inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS)
- Monitors disease activity and response to therapy in IBD patients.
- Programme will cover all assays – Lab and POCT
 - ELISA (enzyme-linked immunosorbent assay)
 - Chemiluminescent immunoassays
 - Point-of-care tests
- Samples distributed will mimic a patient sample appropriate to the method in use

POCT Haematology

- **Full Blood Count**
- **Haemoglobin (Hb) / Haematocrit (Hct):**
 - Rapid detection of anemia or acute blood loss (e.g., trauma, surgery, GI bleeding).
 - Guides transfusion decisions or urgent intervention.
- **White Blood Cell (WBC) count:**
 - Detects infection, sepsis, or inflammation.
 - Early identification supports timely antibiotic therapy or escalation of care.
- **Platelets (PLT):**
 - Critical in bleeding risk assessment, especially for patients on anticoagulants or with thrombocytopenia.
 - Immediate knowledge can guide surgical decisions or platelet transfusion
- **White cell differential (3-part or 5-part diff)**
 - Provides granulocyte (Neutrophils, Eosinophils, Basophils), lymphocyte, monocyte counts
 - Help distinguish bacterial vs viral infection.
 - Monitor immune responses in sepsis, chemotherapy, or immunosuppressed patients.

POCT ACT

- **ACT – Actual Clotting Time**
- ACT measures the time it takes whole blood to clot after exposure to an activator
- It reflects the overall function of the intrinsic and common coagulation pathways
- ACT is widely used to monitor anticoagulation during procedures requiring high-dose heparin, where rapid feedback is essential.
 - Cardiac surgery with cardiopulmonary bypass (CPB)
 - Percutaneous coronary interventions (PCI) such as angioplasty and stenting
 - Extracorporeal membrane oxygenation (ECMO)
 - Haemodialysis and other extracorporeal therapies requiring anticoagulation

Future possibilities

- Alzheimer's / Dementia markers
- Calculated Parameters: AKI, KFRE, FIB4, COLOFIT algorithm
- H Pylori
- Tetanus
- FebriDx
- Legionella
- Strep *pneumoniae*

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If there are any other programmes you would like Weqas to offer, please share them in the questions area