

#### New solutions to chronic urological conditions

Presented by

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Regenerus Laboratories



#### Learning Objectives

- Regenerus Labs
- About MicroGenDX
- Culture Vs MicroGenDX with Chronic UTIs
- MicroGenDX Tests
- Dickson's Pharmacy



# regenerus labs powered by OMNOS\*\*

Supporting health professionals and their patients across the UK and throughout Europe



## We partner with leading laboratories world wide to provide a broad range of comprehensive functional tests

How we support you:



Dedicated Clinicial Support



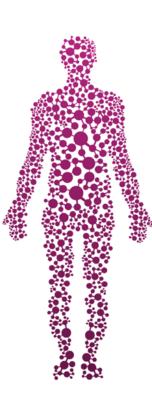
Exclusive Promotions from our partnering labs



Fast and reliable UK and EU shipping



Inclusive interactive data management platform

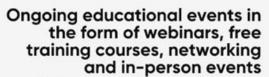


#### Our tests cover:

- Autoimmunity
- Blood Chemistry
- Brain Health
- Cardiometabolic
- Gastrointestinal
- Genetics
- Hormones
- Intolerance & Allergy
- Envrionmental Toxicity
- Nutrition & Toxic Elements
- Thyroid



## What support do **WE PROVIDE**



Well-resourced learning hub to aid practitioner education on a range of relevant health topics





#### Customer service support

Express shipping within the EU via DHL medical express -24 HR SLA's

Network of phlebotomy centres to aid with blood draws within the UK. EU to follow soon





Dedicated Clinician Education team to help HCP with free discovery calls to help choose the right test for their clients

Free support calls post testing to help with test interpretation

#### About MicroGenDX

- MicroGenDX mission is to improve clinical outcomes by offering clinicians and their patients the most informative and impactful microbial diagnostic tests that science can provide.
- MicroGenDXis a college of American Pathologies (CAP) accredited and Clinical Laboratory Improvements (CLIA) licensed clinical laboratory with more than 12 years of experience in diagnosing molecular-based, laboratory-developed tests.
- MicroGenDX operates a high-complex diagnostic laboratory that uses State-of-the-art qPCR+NGS (Next Generation Sequencing) with a database of over 50,000 microbes MicroGenDX identifies bacteria and fungi by PCR and Next Generation Sequencing (NGS) technology.
- MicroGenDX is the only molecular lab that has published randomized outcome studies showing
  its test is superior to culture, as defined by relief of symptoms.



#### **Standard Culture**

#### **Accuracy**

 Studies show that culture may miss up to 50% of UTI cases and only a 30% chance of finding the dominant species that is driving the infection.

#### **Anaerobic bacteria**

• Anaerobic bacteria are difficult to culture, because they don't thrive in an oxygenated environment

#### **Contamination**

• Uncommon, unidentified bacteria are considered contamination – but may in fact be the cause of symptoms.

#### **Antibiotics**

 Often prescribed without knowing the efficacy or purely based on symptoms alone. This can lead to antibiotic resistance.



#### regenerus labs

#### MicrogenDX (PCR NGS)

#### **Accuracy**

- Only US molecular micro lab with 12 years CAP proficiency with a 99.2% accuracy for qPCR and NGS.
- Published research papers.

#### **Anaerobic Bacteria**

Ability to measure aerobic, anaerobic and yeast – using DNA.

#### **Contamination**

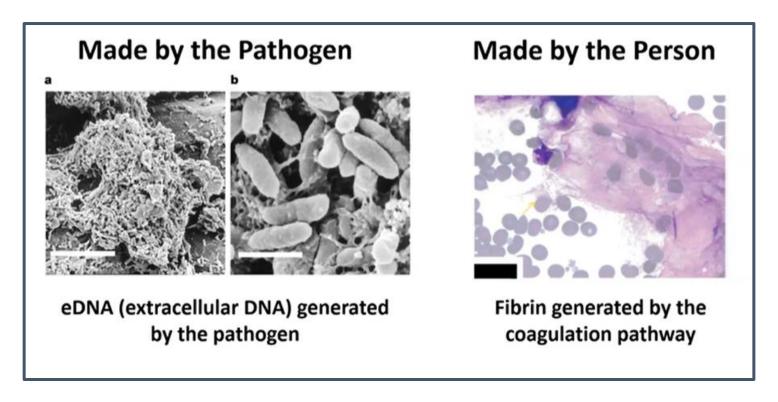
- PCR probes to identify 23 pathogens.
- NGS cross checks sample against a database of more than 50,000+ microorganisms.

#### **Antibiotics**

 Ability to identify drug resistant genes and antibiotics that are effective for each bacteria and yeast.

#### **Biofilms**

#### **How are Biofilms Made**



Contain a community of aerobic, anaerobic bacteria, and yeast living harmoniously.



## How Biofilms Protect Microbes Create Resistance and Drive Chronic UTIs

### Biofilms are highly sophisticated and are extremely good at creating antibiotic resistance

- Communication within the biofilm wall to resist antibiotics
- Pump antibiotic out of the biofilm
- Create a different pH to the rest of the gut so the antibiotic is less effective

Majority of bacteria, yeast linked with chronic UTIs are encased in biofilms





#### **Biofilm Disruptors**

Biofilms in the bladder are different to that in the gut and require different disruptors

- Biofilms Phase 2 Advance Priority 1
- Biofilm Defence Kirkman
- LumbroKinase Dr Mercola

SOURCE: Ruth Kriz, MSN, APRN

#### MicroGenDX Research



#### Mid-stream culture may be "unsuitable"

MSU protocol misses a significant proportion of bacteria, which include recognized uropathogens, and may be unsuitable for excluding UTI in patients with LUTS.

- Routine MSU culture failed to detect a variety of bacterial species, including recognized uropathogens
- 10% of patients with a clinically suspected UTI had positive culture results; 97% of these patients had positive DNA sequencing results



Journal of

Clinical Microbiology

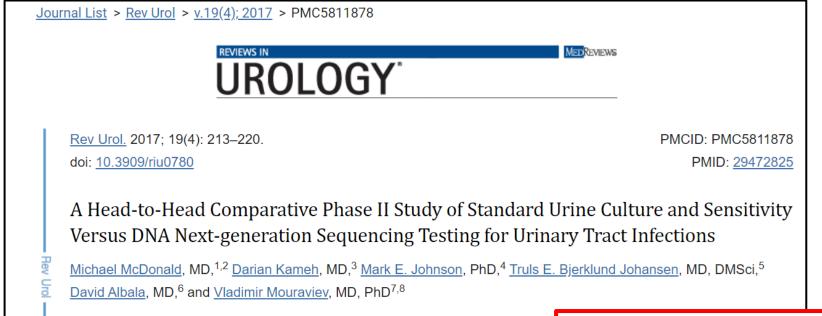
#### MicroGenDX Research

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Abstract





Disclaimer

In total, 13 of 44 were positive from culture. Whereas 44 of 44 patients had positive using PCR/NGS.



#### MicroGenDX Case Study

#### URINE CULTURE - Refle

Test Result

Total Colony Count: 10,000 - 25,000 CFU/mL

#### Organism 1: ESCHERICHIA COLI

Organism Comments: SIND+, BH, FLF, ORG–EC/GNS 77
Organism Colony Count: 10,000 - 25,000 CFU/mL

Sensitivity Organism 1

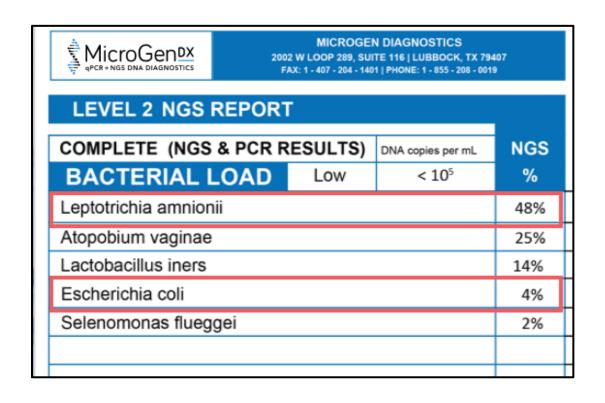
#### Patient did not respond to treatment based on culture

Traditional culture report showed *E-coli* 

- E-coli was treated based on the antibiotic sensitivities
- Patient did not respond



#### MicroGenDX Case Study



## NGS identified the cause for the unresolved UTI symptoms – <u>Leptotrichia</u> amnionii

- Traditional Urine sample sent for DNA sequencing after treatment based on culture results failed
- Proper antibiotic administered for Leptotrichia amnionii and patient recovered



#### MicroGenDX – 1-stage Testing

Stage 1 uses targeted PCR probes to identify 23 pathogens (22 bacteria and 1 yeast)

Escherichia coli
Enterococcus Faecalis
Gardnerella vaginalis
Mobiluncus curtisii
Mobiluncus mulieris
Mycoplasma hominis
Mycoplasma genitalium
Klebsiella Pneumoniae

Prevotella bivia
Pseudomonas aeruginosa
Proteus Mirabilis
Staphylococcus aureus
Staphylococcus Saprophyticus
Streptococcus agalactiae
Trichomonas Vaginalis

Ureaplasma urealyticum
Ureaplasma parvum
Lactobacillus gasseri
Lactobacillus crispatus
Lactobacillus acidophilus
Candida albicans (fungus)
Chlamydia trachomatis
Neisseria gonorrhoeae

 Limitations with PCR is that it will only find what you tell it to look for. If the Bacteria or Yeast that is causing the infection isn't on the list – the cause of the infection will still be missed.

#### MicroGenDX – 2-stage Testing

Stage 2 – Next Generation Sequencing (NGS)

 NGS is more comprehensive than PCR - it looks at all the genetic material (16s gene common to all bacteria and 18s gene common to all yeast) contained within a sample against a database of 50,000+ microorganisms.

#### MicroGenDX Level 1 Sample report

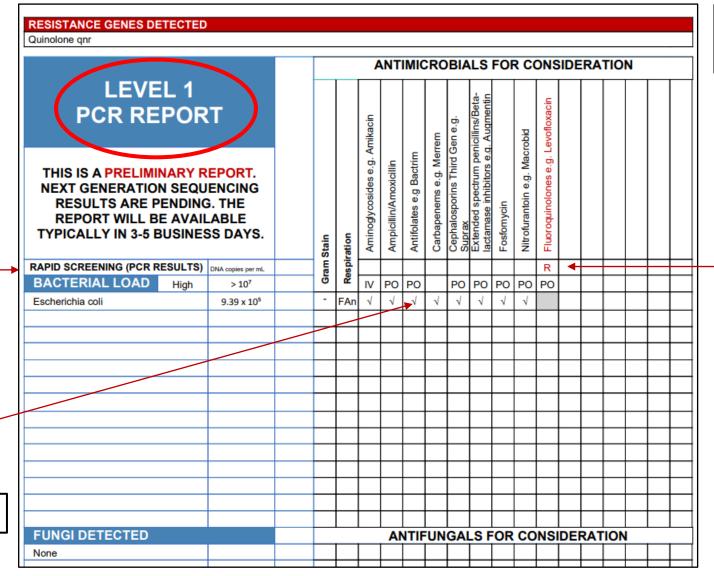




- Bacteria load by species
- Gram Strain (-/+)

Tick indicates
Antibiotic sensitivity

List of yeast if detected



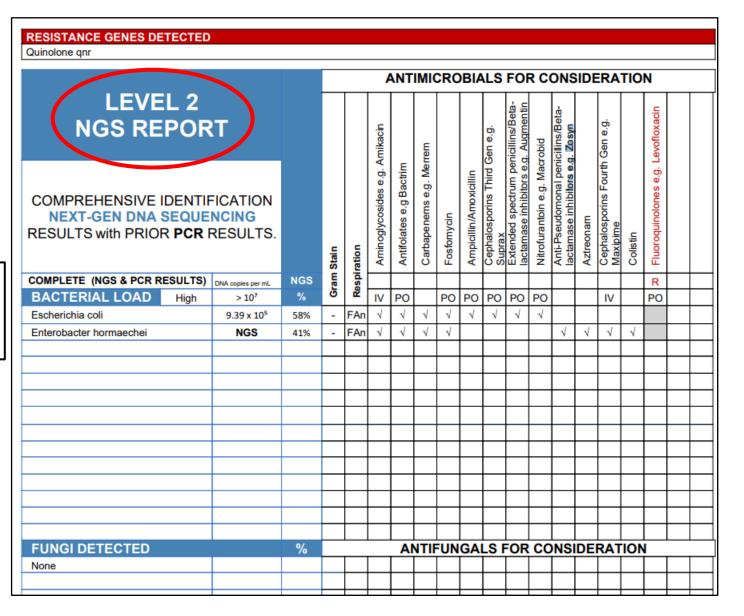
Resistance Genes Detected

Antibiotic Resistance

#### MicroGenDX Level 2 Sample report



- List bacteria identified in level 1 PCR
- List bacteria identified by NGS



#### **MicroGenDX** Tests

- UroKey
- WomensKey Complete
- MensKey Complete



#### MicroGenDX UroKey

**Sample Requirement:** Midstream urine sample

**Turn Around Time:** 3-7 Days. Level 1 report is done first, followed by Level 2

Price: £225 Trade £280 RRP

Test code: MG003

#### **Target Patients:**

- UTI symptoms but negative culture results
- Chronic/recurrent UTIs
- Previous Antibiotic therapy still have symptoms
- interstitial cystitis



#### MicroGenDX WomensKey Complete

**Sample:** Midstream Urine and semen sample

Turn Around Time: 3-7 Days. Level 1 report is done first, followed by Level 2

Price: £384 Trade £480 RRP

Test code: MG001

#### **Target Patient:**

- UTI symptoms but negative culture results
- Chronic/recurrent UTIs
- Previous antibiotic therapy still have symptoms
- Interstitial cystitis
- Bacterial vaginosis
- Reproductive system Infections
- Yeast infections



#### MicroGenDX MensKey Complete

**Sample:** Midstream Urine and semen sample

**Turn Around Time:** 3-7 Days. Level 1 report is done first, followed by Level 2

Price: £384 Trade £480 RRP

Test code: MG001

#### **Target Patient:**

- UTI symptoms but negative culture results
- Chronic/recurrent UTIs
- Previous Antibiotic therapy still have symptoms
- Interstitial cystitis
- Prostatitis



### Dickson Pharmacy dickson

 "Dickson Pharmacy is an award winning, independent pharmacy chain that consists of 9 NHS pharmacies and 1 private dispensing facility. We have been dispensing private prescriptions for over 15 years and pride ourselves on our ability to deliver a seamless, accurate and fast service. All of our professionals are highly experienced and adopt a holistic and personalised approach to all patients."



#### **Dickson Chemist – Referring patients**



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# Urgent prescriber consultation – general medical services

£50.00







#### **Key Contacts**

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Sales in Europe - Samuel Hagan <a href="mailto:shagan@regeneruslabs.com">shagan@regeneruslabs.com</a>

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## Thank you