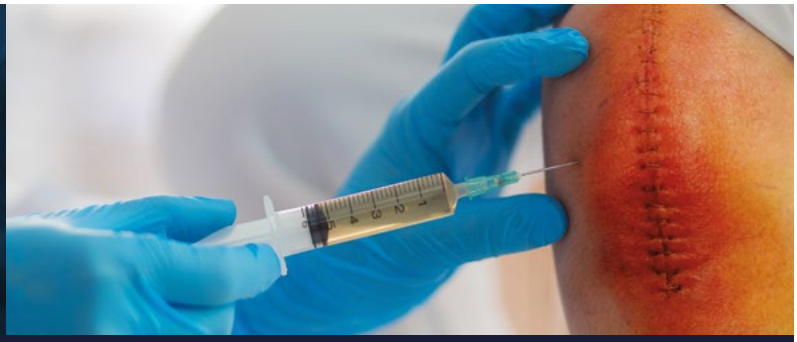


ORTHOKEY® by MicroGenDX SURGERY

ORTHOKEY® by MicroGenDX CLINIC

NEW! All-in-one diagnostic tool from MicroGenDX

OrthoKEY combines synovial biomarkers and molecular technologies with an innovative DNA collection swab

To treat periprosthetic joint infections (PJIs) effectively, you need to know if a joint is infected and which pathogens are causing the infection.

Introducing OrthoKEY from MicroGenDX, your all-in-one diagnostic tool — a single test for surgery or clinic that combines biomarkers for diagnosis of infection with the best molecular technologies available to identify causative pathogens.

Featuring:

- Synovial biomarkers (SF-CRP, SF-WBC, SF-PMN%) and resistance genes (results emailed in **1-2 days**)
- Full NGS analysis (results emailed in **3.5 days**)
- An innovative CaptiGen® flat swab, tailored for DNA collection from biofilm
- The PJIDx diagnostic app that provides AI-driven and evidence-based guidance for diagnosis of PJI based on your OrthoKEY test results

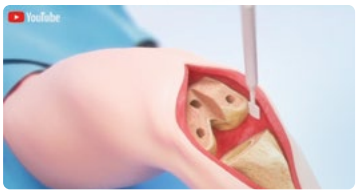
Resulting in:

- ICM criteria-compliant diagnostics for culture-negative PJIs

  A strong consensus of 2018 ICM delegates states that molecular diagnosis should be used to isolate pathogens causing PJI.[1]
- More exhaustive results in tandem with culture
- Potential detection of untreated/undertreated persistent infections

  In 2020 a prospective multicenter study demonstrated that 68.6% of revision failures following two-stage exchange were due to untreated or undertreated pathogens that were missed by culture, but detected by NGS at the time of initial resection.[2]

OrthoKEY Surgery



Scan QR code with your phone to **view sampling techniques**

Or go to microgendx.qrd.by/ortho-sample

OrthoKEY Clinic

Get more answers.
www.MicroGenDX.com
info@microgendx.com
855.208.0019

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS

CLIA Certified

OrthoKEY Surgery and OrthoKEY Clinic from MicroGenDX

Synovial biomarkers + qPCR + NGS = ***informed clinical decisions & improved patient outcomes***

Life-altering and life-threatening PJIs demand the best diagnostic technology

NEW! Combined synovial biomarkers plus molecular analyses

OrthoKEY employs **2018 ICM diagnostic criteria.** The report includes:

- Actual biomarker values
- Species-level NGS results
- Multiplex PCR results
- Detection of resistance genes

SUMMARY OF RESULTS

BIOMARKER RESULTS	
MARKER	RAW VALUE
Synovial CRP:	_____mg/L
Synovial WBC:	_____cells/uL
Synovial PMN %:	_____% PMN
NGS RESULTS	
NEGATIVE	

RISK FOR INFECTION*	
HIGH PROBABILITY OF INFECTION	Based on the information provided, the risk of infection per 2018 ICM criteria is inconclusive. Further work-up in keeping with the criteria listed in Result Detail is needed.

*Risk calculated from 2018 ICM definition with positive NGS results as proxy for single positive culture. NGS is not part of the 2018 ICM definition. Calculated probability of infection does not incorporate serum markers. If CRP and/or ESR are positive, probability of infection is higher than reported above.

CUTOFF	ICM 2018 SCORE ATTRIBUTED
Chronic PJI threshold = >4.2 mg/L	1 point
Chronic PJI threshold = >2,000 cells/uL	3 points
Chronic threshold = >70% PMN	2 points

SUMMARY OF MULTIPLEX PCR RESULTS (LEVEL 1)	
Organism 1	Staphylococcus aureus
Organism 2	
Organism 3	
SUMMARY OF NGS PATHOGEN IDENTIFICATION (LEVEL 2)	
Organism 1	Staphylococcus aureus
Organism 2	
Organism 3	
RESISTANCE GENES DETECTED	
Organism 1	Methicillin
Organism 2	
Organism 3	

NEW! The CaptiGen® flat swab for surgery

- Designed for optimized NGS, RT-PCR, and culture yield
- Validated for efficient extraction of DNA from biofilm
- Validated for 36-hour dry specimen hold at room temperature
- Ejector tip minimizes cross-contamination

MicroGenDX is ideal for diagnosis of chronic and acute infections

- **24–48** hour turnaround time for synovial biomarkers (SF-CRP, SF-WBC, SF-PMN%) and 17 antimicrobial resistance genes
- **3.5 days** turnaround for complete NGS identification of pathogens to the species level
- Detection of pathogens in 80-90% of culture-negative PJIs
- More than 500,000 qPCR+NGS samples processed
- $299 for hospitals, with office and clinic use covered by insurance
- The most (70+) published studies of any molecular lab
- 11 years CAP proficiency testing with results showing **99.2% accuracy**[3]

Contact your MicroGenDX representative or our customer service department to order supplies or for more information.

MicroGenDX
qPCR + NGS DNA DIAGNOSTICS
FOR ACCURATE MICROBIAL IDENTIFICATION

Get more answers.
www.MicroGenDX.com
info@microgendx.com
855.208.0019

1. 2018 International Consensus on Orthopedic Infections, super majority strong consensus: 85% synovial biomarkers and NGS are powerful tools for culture-negative PJIs; 92% synovial biomarkers improve diagnostic accuracy for PJIs; 93% NGS can help inform PJI therapeutic choices.
2. https://www.odtmag.com/contents/view_breaking-news/2020-09-16/next-generation-sequencing-predicts-failure-in-total-joint-arthroplasty/ Multicenter data also presented at 2019 AAHKS
3. College of American Pathology proficiency results, 2009–2019

5826 Hoffner Ave, Suite 1004, Orlando, FL 32822
11/20