

**CLIN-PATHO<sup>SM</sup> REPORT**
**Patient**

 [REDACTED]  
 Gender: Fe  
 Patient ID: [REDACTED]  
 Request ID: [REDACTED] 111

**Ordering Provider**

[REDACTED]

**Sample Information**
**Urine DNA**  
 Specimen#: 11790504  
 Collected: 02/20/2021  
 Received: 02/24/2021  
 Reported: 03/08/2021

**CLIN-PATHO<sup>SM</sup> SUMMARY**

DNA Viruses Identified	<b>Detected</b>	Total DNA Fragments	41,871,632
Parasite & Other Identified	<b>Detected</b>	Human DNA Fragments	17,405,928
Fungi Identified	<b>Detected</b>	Total Classified DNA Fragments	5,195,848
Bacteria Identified	<b>Detected</b>	Microbial Burden	20.697%

**FINDINGS**

The findings of this test are POSITIVE. Microbial burden is higher than expected in healthy female urine, suggesting significant microbial overgrowth. Uropathogens are present at elevated levels. Evidence of infection is present.

Clin-PATHO™ Urine Test identifies every known, sequenced microorganism physically collected in the urine sample tested. Sample collection procedure, patient history, diet/dietary supplements, occupation, and exposures should be taken into consideration when reviewing findings. If infection is present, sexual partners should be evaluated as a possible reservoir of re-infection. This summary is based on the current understanding of female urinary microbiomes and scientific knowledge of microorganisms, which regularly evolves, and views may change over time.

**PATHOGENS**

Propionimicrobium lymphophilum was identified at high levels and has been documented in urinary tract infections (<https://jcm.asm.org/content/53/9/3077>).

**POTENTIAL PATHOGENS**

Actinotignum timonense was identified at high levels and is not found at high levels in healthy female urine. Related species have been documented to cause UTIs (<https://pubmed.ncbi.nlm.nih.gov/26577137/>).

Prevotella species were identified at higher levels than expected in healthy urine and have been documented in UTI cases (<https://onlinelibrary.wiley.com/doi/full/10.1111/j.1442-2042.2003.00756.x>).

Peptoniphilus was higher than expected and a documented uropathogen (<https://www.mathewsopenaccess.com/full-text/cutaneous-vasculitis-as-a-first-sign-of-isolated-peptoniphilus-spp-in-urinary-tract-infection-a-case-report>).

Porphyromonas, Varibaculum, and Aerococcus were all higher than expected and known uropathogens.

**OTHER MICROORGANISMS**

Many enteric bacteria, archaea, and fungi were identified at low levels, some of which are not expected in healthy urine. These may have been introduced into the sample if clean-catch instructions were not followed. They may also be colonizing the bladder/urethra if a clean catch was taken. A number of healthy urinary flora were identified at low levels.

Reviewed by: Crystal R Icenhour, PhD – CEO, Infectious Disease Expert

Approved by: C Alexander Valencia, PhD - CCO and Laboratory Director

Approved by: Yaping Qian, PhD - Laboratory Director

Note: This summary of findings is intended to give clinicians information to gain a deeper understanding of the microbial populations identified in each sample tested. This summary of findings highlights microorganism(s) presence and abundance, compared to healthy samples and relevant peer-reviewed literature. We can provide additional support to clinicians on a case-by-case basis, however, it is beyond our scope of practice to provide diagnosis, drug susceptibility, or treatment guidance. It is recommended that a pharmacist with expertise in infectious diseases be consulted with regard to treatment guidance. If you would like to schedule an appointment to speak to one of our infectious disease experts, please email [support@aperiomics.com](mailto:support@aperiomics.com).

**CLIN-PATHO<sup>SM</sup> IDENTIFIED DNA VIRUS**

Species	RPM
<i>Staphylococcus phage Twillingate</i>	342
<i>Streptococcus phage Javan32</i>	295
<i>Staphylococcus phage Quidividi</i>	121
<i>Staphylococcus virus CNPH82</i>	15

### CLIN-PATHO<sup>SM</sup> IDENTIFIED PARASITE & OTHER

Kingdom	Species	Abundance %	RPM
Archaea	<i>Methanobrevibacter smithii</i>	0.294	1946.17
Archaea	<i>Methanobrevibacter sp. A54</i>	0.002	15.782

### CLIN-PATHO<sup>SM</sup> IDENTIFIED FUNGI

Species	Abundance %	RPM
<i>Saccharomyces cerevisiae</i>	0.001	26.175

### CLIN-PATHO<sup>SM</sup> IDENTIFIED BACTERIA

Species	Abundance %	RPM
<i>Propionimicrobium lymphophilum</i>	9.1	81979.3
<i>Actinotignum timonense</i>	5.3	45760
<i>Prevotella timonensis</i>	5.1	63035.7
<i>Peptoniphilus harei</i>	5	34435.2
<i>Prevotella corporis</i>	5	53213.6
<i>Porphyromonas uenonis</i>	4.5	43268.4
<i>Porphyromonas somerae</i>	4.4	40782.9
<i>Porphyromonas asaccharolytica</i>	3.9	37565.8
<i>Prevotella buccalis</i>	3.7	43951.6
<i>Varibaculum cambriense</i>	3.5	34223.9
<i>Aerococcus urinae</i>	3.3	26623.6
<i>Anaerococcus lactolyticus</i>	2.9	23629.6
<i>Peptoniphilus lacrimalis</i>	2.7	18640.7
<i>Fingoldia magna</i>	2.6	18858.5
<i>Streptococcus dysgalactiae</i>	2.6	20003.7
<i>Campylobacter ureolyticus</i>	2.6	16383.9
<i>Porphyromonas bennonis</i>	2.5	20412.5
<i>Prevotella colorans</i>	2.2	24175.1
<i>Varibaculum massiliense</i>	1.4	16454.3
<i>Mobiluncus curtisii</i>	1.4	14921.5

Species	Abundance %	RPM
<i>Fenollaria timonensis</i>	1.2	7924
<i>Peptoniphilus grossensis</i>	1.2	9476.4
<i>Facklamia hominis</i>	1.2	7872.1
<i>Corynebacterium imitans</i>	1	11225.5
<i>Levyella massiliensis</i>	1	6181.5
<i>Atopobium deltae</i>	0.8	4352.7
<i>Lagierella massiliensis</i>	0.8	6122.2
<i>Peptoniphilus pacaensis</i>	0.8	5306.9
<i>Alterileibacterium massiliense</i>	0.7	4009.7
<i>Anaerococcus obesiensis</i>	0.7	5473.6
<i>Corynebacterium aurimucosum</i>	0.7	8290.9
<i>Corynebacterium frankenforstense</i>	0.6	6372
<i>Porphyromonadaceae bacterium FC4</i>	0.6	4655.6
<i>Bacteroides vulgatus</i>	0.6	10467.2
<i>Ezakiella massiliensis</i>	0.5	3410.4
<i>Corynebacterium jeikeium</i>	0.5	5161.8
<i>Peptococcus niger</i>	0.5	3653.3
<i>Clostridiales bacterium S5-A14a</i>	0.5	3057.8
<i>Peptoniphilus urinimassiliensis</i>	0.5	3319.2
<i>Corynebacterium glucuronolyticum</i>	0.5	5047.5
<i>Anaerococcus prevotii</i>	0.4	2948.9
<i>Corynebacterium tuberculostearicum</i>	0.4	3445.8
<i>Lachnospiraceae bacterium 3_1_46FAA</i>	0.4	4183
<i>Tissierellia bacterium S7-1-4</i>	0.4	2939.3
<i>Fusobacterium naviforme</i>	0.4	3053.2
<i>Corynebacterium pseudogenitalium</i>	0.3	3405.8
<i>Anaerococcus vaginalis</i>	0.3	2205.2
<i>Corynebacterium pyruviciproducens</i>	0.3	3285.7
<i>Gleimia europaea</i>	0.3	2434.3
<i>Tissierellia bacterium S5-A11</i>	0.3	3182.2
<i>Campylobacter hominis</i>	0.2	1502
<i>Prevotella bergensis</i>	0.2	2996.2
<i>Staphylococcus epidermidis</i>	0.2	2041.6
<i>[Bacteroides] coagulans</i>	0.2	1594.3
<i>Corynebacterium ihumii</i>	0.2	2269.5

Species	Abundance %	RPM
<i>Peptoniphilus obesi</i>	0.2	1224.8
<i>Varibaculum vaginae</i>	0.2	2148.3
<i>Anaerococcus mediterraneensis</i>	0.2	1460
<i>Peptoniphilus vaginalis</i>	0.2	1167.1
<i>Anaerococcus marasmi</i>	0.2	1323.4
<i>Urinicoccus massiliensis</i>	0.1	1174.4
<i>Corynebacterium coyleae</i>	0.1	2006.6
<i>Bacteroides dorei</i>	0.1	2509.3
<i>Corynebacterium minutissimum</i>	0.1	1523.9
<i>Corynebacteriaceae bacterium 'ARUP UnID 227'</i>	0.1	1259.9
<i>Winkia neuii</i>	0.1	1030.1
<i>Faecalibacterium prausnitzii</i>	0.1	1497.3
<i>Bacteroides uniformis</i>	0.1	2197.5
<i>Escherichia coli</i>	0.1	2272.6
<i>Blautia obeum</i>	0.1	1621.7
<i>Anaerococcus provencensis</i>	0.1	1069.7
<i>Arcanobacterium urinimassiliense</i>	0.1	793.3
<i>Anaerococcus urinomassiliensis</i>	0.1	1050.8
<i>Anaeroglobus geminatus</i>	0.1	762.1
<i>Megasphaera massiliensis</i>	0.1	1135.9
<i>Ektepia gabavorous</i>	0.1	1012.3
<i>Acidaminococcus intestini</i>	0.1	966.9
<i>Ruminococcaceae bacterium cv2</i>	0.1	1659.4
<i>Ezakiella peruensis</i>	0.1	691.3
<i>Peptoniphilus senegalensis</i>	0.1	772.5
<i>Corynebacterium hadale</i>	0.1	1386.9
<i>Anaerococcus octavius</i>	0.1	592.4
<i>Bacteroides ovatus</i>	0.1	1913.1
<i>Bacteroides thetaiotaomicron</i>	0.1	1746
<i>Negativicoccus succinicivorans</i>	0.1	404.9
<i>Parabacteroides distasonis</i>	0.1	1351.8
<i>Enterococcus faecalis</i>	0.1	832.2
<i>Clostridiales bacterium SIT11</i>	0.1	466.5
<i>Blautia massiliensis</i>	0.1	930.4
<i>Corynebacterium jeddahense</i>	0.1	1083.9

<b>Species</b>	<b>Abundance %</b>	<b>RPM</b>
<i>Parabacteroides merdae</i>	0.1	1081.2
<i>Corynebacterium genitalium</i>	0.1	739.1
<i>Olegusella massiliensis</i>	0.1	440
<i>Corynebacterium amycolatum</i>	0.1	605.1
<i>Desulfovibrionaceae bacterium</i>	0.1	856.1
<i>Kallipyga massiliensis</i>	0.1	428.8
<i>Alistipes finegoldii</i>	0.1	797.9
<i>Anaerococcus hydrogenalis</i>	0.1	555.1
<i>Peptoniphilus duerdenii</i>	0.1	492.7
<i>Coprococcus catus</i>	0.1	677.8
<i>Fastidiosipila sanguinis</i>	0.1	406.5
<i>Facklamia ignava</i>	0.1	331.8
<i>Facklamia languida</i>	0.1	314.9
<i>Fenollaria massiliensis</i>	0.1	333

## METHODS

Total DNA was isolated using commercial DNA extraction kits from each sample type. Libraries were prepared using the KAPA HyperPlus Prep Kit (Roche, Wilmington, MA) followed by fluorometry DNA quality quantification assessment and shotgun metagenomic sequencing on NextSeq500 or HiSeq2500 (Illumina, San Diego, CA) using 75 bp paired-end or 100 bp paired-end modes. For shotgun metagenomic sequencing analysis, Xplore-ID software and Xplore-DB database (Aperiomics, Inc., Sterling, VA) were utilized for quality assessment, background removal, alignment, genome binning, microbial identification, and abundance / RPM calculations.

## DEFINITIONS

- **SHOTGUN METAGENOMICS SEQUENCING** - A DNA sequencing method where millions of sequencing reactions are carried out in parallel, increasing the sequencing throughput and generating a raw DNA data file for DNA present in the sample. This method allows unbiased sequencing of all or nearly all DNA in a sample, including microbial genetic information.
- **XPLORE ID** - Analysis software that rapidly and accurately defines the proportions of reads from individual microbial species present in shotgun metagenomic sequencing data obtained from samples.
- **XPLORE DB** - A comprehensive database containing the complete genomes of every high quality, validated genome from every sequenced microorganism.
- **TOTAL DNA FRAGMENTS** - The shotgun sequencing output total number of DNA fragments sequenced.
- **HUMAN DNA FRAGMENTS** - The number of DNA fragments that specifically match to the host. The host in most clinical samples is human.
- **CLASSIFIED DNA FRAGMENTS** - The reads that align to any known microorganism.
- **RPM (Read Per Million)** - The number of reads mapped to a genome per million microbial DNA reads in the sample.
- **MICROBIAL BURDEN** - Microbial Burden is the number of microbial reads found compared to the total host and microbial reads. Microbial burden can mean different things based on what type of sample is being examined. This can sometimes be above 0% in a sample with no microbes due to sequencing noise.
- **ABUNDANCE** - The Abundance % category is the estimated amount of [microbial DNA that matches each listed species] in the sample compared to other microbes present. The relative abundance is defined as:

$$S_i = \frac{C_i/g_i}{\sum C_i/g_i}$$

where  $i$  represents the index of the given species;  $S$  is the relative abundance;  $C$  is number of reads assigned to the given species;  $g$  is the size of the reference genome (bp). Because virus genome size is very small, viruses are not included in this calculation to prevent bias.

## LIMITATIONS OF THE TESTS AND ADDITIONAL INFORMATION

While the results of **CLIN-PATHO<sup>SM</sup>** testing is accurate, the presence and/or absence of microorganisms may vary due to a number of circumstances. Such circumstances may include sample collection procedure, use of probiotics and anti-infective medications, and other factors. Samples testing positive for potential pathogens should be referred to a healthcare provider for interpretation of the results in relation to all other clinical symptoms and testing. The results of this testing, including the benefits and limitations, should be discussed with a qualified health care provider and are required for diagnosis and treatment. The healthcare provider is responsible for the use of this information in the management of their patient. Pursuant to the requirements of CLIA '88, this test was developed and its performance validated by Aperiomics. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. Aperiomics CLIA number is 49D2181329. Aperiomics, Inc. is required by law to maintain the privacy and security of your protected health information. **APERIOMICS<sup>®</sup> is trademark of Aperiomics, Inc. © 2020 Aperiomics, Inc All rights reserved.**