



OFFICE SOLUTION PROGRAM
FOR MOLECULAR/PCR TESTING
UTI Clinical Utility and Testing

UTI TESTING

THE FACTS ABOUT UTIs



SECOND MOST COMMON INFECTION IN THE USA.



50% OF ALL SEPSIS CASES AMONG NURSING HOME RESIDENTS ORIGINATE FROM UTIS



COMPLICATED OR UNTREATED UTIS FREQUENTLY CAUSE SEPSIS IN OLDER ADULTS ABOVE 65 YEARS OF AGE WITH MORTALITY RANGING FROM 25-60%.



60% OF ALL WOMEN WILL DEVELOP A UTI DURING THEIR LIFETIME



13 BILLION DOLLAR IMPACT ON THE HEALTHCARE SYSTEM



MOST COMMON CAUSE OF BACTERIAL INFECTIONS IN LONG-TERM CARE FACILITIES

UTI TESTING

URINE PCR vs CULTURE

Why PCR?

- Standard Microbiology culturing looks for only 5 or 6 pathogens with 29% error rate.
- Standard Microbiology sensitivity testing evaluates only 6 or 7 antibiotics, while Antibiotic resistance to pathogens continues to increase.
- Less stringent swab storage requirement.
- Identifies mixed infection with better accuracy and specificity.
- Minimize the false negative which are common with traditional methods due to error in collection, storage and transport.
- Comprehensive Panel of Targets—Detect a broad range of targets.
- Rapid Turn-Around-Time.

Why Urine Culture is not always optimal for UTI?

- Slow and time consuming
- Methods developed for specific species and strains
- A few environmental mutant strains may not grow.
- Non-mature and stressed cells (VBNC) can be undetectable.
- Background flora competence can lead to growth inhibition.
- Result interpretation relies on analysts' experience and skills
- False negatives or underestimations can occur.

UTI TESTING

ANTIBIOTICS RESISTANCE MARKER (ABR)

- ABR are gene or gene mutation present in pathogens that can lead to drug resistance.
- ABR panel consists of a combination of these ABRs that can help to identify the resistance to a drug or class of drugs.
- ABR panel works on exclusion strategy. A positive ABR test helps to eliminate the use of a drug. The negative results do not confirm the sensitivity to a drug.
- ABR panels are designed by curating the available clinical information.
- ABR panel works on reflex method. Based on PCR ID results, a single or group of ABR panels are reflexed for testing.

The clear distinction between conventional antibiotic susceptibility testing and molecular resistance marker is a difference of antibiotic inclusion versus antibiotic exclusion prescription strategy. Detecting genetic resistance provides information to clinicians so that they may avoid an antibiotic class for which a resistance gene may exert its effects during treatment of the infectious process.



OUR SOLUTION

PROGRAM INCLUDES THE FOLLOWING:

- Laboratory Application Process - Submission and Follow-Up for Lab Licensure and Proficiency Testing (Does Not Include Actual Licensure Fees)
- Equipment Delivery, Set-up, Installation, Validation Compliance
- Complete Laboratory Set-up, CLIA Compliance Manuals, On-Going Compliance Oversight/Maintenance, Site Preparation and Workflow Design.
- On-site Presence and Support for Laboratory Inspections & Compliance.
- Full Equipment Service & Support Warranty - Business Hours Mon - Fri 8am-5pm, excluding weekends and holidays. Labor, travel and service parts included.
- Unlimited Phone Technical Support
- All Reagents, Controls, Calibrators and Analyzer Consumables needed as per Program.

UTI

THE INSTRUMENT

SPECIFICATION SHEET

QuantStudio 5 Real-Time PCR System for Human Identification

QuantStudio 5 Real-Time PCR System for Human Identification

The Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System for Human Identification (HID) is the latest addition to the Applied Biosystems™ HID quantification solutions. This instrument is designed for both new and experienced users who need a simple, reliable, and affordable real-time PCR system without compromising performance or quality. Combined with our latest advancements in quantification chemistries and real-time software, this system equips laboratories for future advancements in forensics—offering maximum dye versatility while offering accurate, trusted results.



QuantStudio 5 Real-Time PCR System for forensic applications	
Forensic database	Laboratories without direct amplification workflows
Forensic casework	Confirmatory screening of male DNA Sexual assault sample workflow
	Quality and quantity sample assessment

Additional application possibilities on the QuantStudio 5 Real Time PCR System				
Key areas	Gene expression	Genotyping	Copy number variation (CNV)	miRNA profiling

QuantStudio 5 Real-Time PCR System for Human Identification specifications	
Excitation (light source)	Bright white light emitting diode (LED) source with a median lifetime >5 years
Dimensions and weight	27 x 50 x 40 cm (W x D x H), <26 kg
Sample capacity (wells)	96-well; 0.2 mL block
Reaction volume	96-well: 10–100 µL for 0.2 mL block
Maximum ramp rate	6.5°C/sec
Average sample ramp rate	3.66°C/sec
Temperature uniformity	0.4°C
VeriFlex™ Blocks	96-well: 6 independent temperature zones
Heating/cooling method	Peltier
Run time	~70 min for Applied Biosystems™ Quantifier™ Trio and HP kits ~100 min for Applied Biosystems™ Quantifier™ Duo and Human kits
Calibration	Factory-calibrated*
Onboard memory	10 GB, which translates to approximately 2,000–5,000 run files
Electrical approvals	IEC, CE

ThermoFisher
SCIENTIFIC

QuantStudio 5 Real-Time PCR System for Human Identification specifications, continued	
Filters/colors	96-well: 6 decoupled filters, up to 21 combinations
Excitation/detection range	96-well: 450–680 nm/500–730 nm
Data acquisition	Whole-plate imaging
Touch screen	Interactive touch screen with real-time application viewing
Online ecosystem*	Thermo Fisher Cloud
Communication interface*	Thermo Fisher Cloud, USB, or Wi-Fi
External devices	2D barcode reader via USB connection
System configuration	Stand-alone, PC connection via Ethernet (colocated) or LAN
International standards	ISO 13485

* Not validated for human identification.

HID Real-Time Software v1.3 PCR specifications	
Component	Recommended requirements
Computer	Dell™ Latitude™ laptop OS: Microsoft™ Windows™ 7 Professional Service Pack 1, 32- or 64-bit Processor: Intel™ Core™ i7-4600M CPU @ 2.90 GHz Installed memory: 16 GB Dell™ OptiPlex™ desktop OS: Windows 7 Professional Service Pack 1, 32- or 64-bit Installed memory: 16 GB
Instrument firmware	Applied Biosystems™ QuantStudio™ 5 real-time PCR system: 1.3.1 or later
Simplified workflow for HID	Predefined templates for HID Quantifier assays
Supported platforms	QuantStudio 5 (96-well, 0.2 mL) and Applied Biosystems™ 7500 real-time PCR systems
Run protocols	Preoptimized run protocols or ability to customize
Key features	Virtual standard curve, short tandem repeat (STR) sample normalization (dilution) and reaction setup, generation of quality flags, calculation of quality value (degradation index) and male:female (M:F) sample mixture ratio
Validation	Validated for the following HID quantification assays (Quantifier Trio, HP, Duo, and Human) on QuantStudio 5 and 7500 platforms

UTI TESTING

PRO FORMA FOR PCR UTI



CLIENT PRO FORMA ANALYSIS

	Monthly	Yearly
Laboratory Director	Included	Included
CLIA Consultant	Included	Included
CLIA/COLA Fees (Fees vary by State)	Paid by Clinic	Paid by Clinic
Med Lab Tech Fees (Fees \$30/Hr/5 days a week)	Paid by Clinic	Paid by Clinic
Monthly Equipment Lease	Included	Included
Cost/Reportable Result (Monthly Invoices)	Paid by Clinic	Paid by Clinic
TOTAL COST of Laboratory	Included	Included
VARIABLES in Laboratory	Weekly	Monthly
Average Number of Samples	25	100

Projected Monthly Net Profit \$35,200.00

Projected Annual Net Profit \$422,400.00

*****EXAMPLE ONLY**

Independent analysis by your own financial team is strongly recommended.



Josh Wilk
630.723.7726
jwilk@infintydxgroup.com

Brian Tierney
616.723.4991
btierney@infinitydxgroup.com

30600 Telegraph Rd
Suite #1375
Bingham Farms, MI 48025