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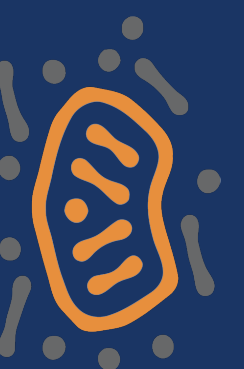
DIAGNOSTICS®

COVID-19 INFECTIOUS DISEASE DIAGNOSTICS

COVID-19 Diagnostics

Advantages of Quantitative PCR (qPCR) -Based Infectious Disease Testing and Diagnostics in Fighting The COVID-19



CORONAVIRUS

COVID-19 INFECTIOUS DISEASE DIAGNOSTICS

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According to the World Health Organization, the CoVs are a large family of single-stranded RNA viruses (+ssRNA) and are enveloped viruses with nucleocapsid.

COVID-19 (Coronavirus) **qPCR** (and RNA) **Level Testing**

CUUR Diagnostics's molecular **qPCR** laboratories are specifically suited to detect and diagnose the CORONAVIRUS (COVID-19).

Our laboratory testing provides superior sensitivity and specificity to identify pathogens, such as COVID-19, using qPCR DNA and RNA level sequencing, resulting in extreme accuracy and diagnosis within hours.

We utilize industry leading equipment including the latest technologies from **ThermoFisher** and operates under the **Emergency Use Authorization (EUA)** guidance issued by the **FDA** and **CAP** and **CLIA** quality standards.

CUUR Diagnostics' national network of laboratories was founded by a physician with the goal of delivering the most state of the art genetic testing with universal insurance acceptance and a focus on customer support.

CUUR Diagnostics is a biotechnology company focused on improving patient, provider and facility healthcare outcomes for Infectious Disease. Our advanced, proprietary solution combines technology, diagnostics, data management, decision platforms and outcomes analysis utilizing Artificial Intelligence (AI). With the largest data set of Infectious Disease targets available in the world, **CUUR Diagnostics** offers tremendous flexibility, extremely precise diagnosis, treatment guidance for patients and improved antibiotic stewardship.

Key Components of CUUR Diagnostics's Molecular Diagnostics Solution:

- Diagnostics with Extreme Sensitivity and Specificity
- Comprehensive Sample Types Including Complicated Biofilms
- Rapid Results in Hours Rather than Days
- Actionable Results to Drive Targeted Treatment Decisions
- Decreased Potential for Human Error
- Fully Integrated IT and Data Outcomes Analyses
- Regulatory and Compliance Protocols
- CLIA and CAP Quality Stardards
- Pharmacy and Experienced ID Expert Advice
- Ongoing Training and Continuing Education
- Reduce Inappropriate Antimicrobial Use and Spread of Resistance
- Research and Development to Drive Future Innovation

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INFECTIOUS DISEASE DIAGNOSTICS

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qPCR Molecular Level Testing

Identifying the RNA COVID-19 with extreme accuracy and speed.

Better Approach than Classical Diagnostics

- High Specificity: Reports precisely which microbes are present
- High Sensitivity: Improved detection rates over classical culture, microscopy and clinical evaluations
- Broad Coverage: Comprehensive tests cover multiple microrganisms from five major target types: bacteria, virus, yeast, protozoa, and mycoplasma/ureaplasma
- Panel Testing: Specific panels can be run individually for pathogen identification or together as a comprehensive screen for reflex determination of antibiotic resistance susceptibility for certain pathogenic targets
- Single Sample: Requires only a single patient sample collection

Methodology

- Real-time PCR uses robust 5' nuclease chemistry
- Small amount of input DNA required
- High sensitivity and specificity
- All assays pre-designed and validated
- Low cost per sample
- Reproducible and empirical
- Easy workflow with rapid, accurate throughput
- Survey multiple pathogens from single sample
- Quantitative results enable comparisons between different samples and with clinical criteria
- Objective scoring, does not require subjective expertise as seen with microscopy
- Identify organisms associated with more than one condition

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Advantages of Quantitative PCR (qPCR) -Based Infectious Disease Testing and Diagnostics

Real-Time Quantitative PCR

Real-time quantitative PCR (qPCR) is a scalable, automated technique that allows for the simultaneous identification and quantification of the microbes present in patient samples.

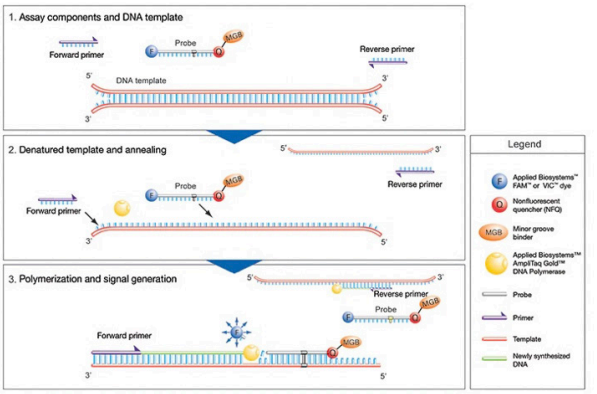
This is achieved by using pathogen specific probes that bind to their "target" species. Through subsequent cycles of PCR amplification, relative fluorescence shows the precise measure of the target amplicon at each cycle. This quantification is highly accurate even at very low levels of infectious organisms, which can reflex for further identification of which antibiotic resistance genes are may be present.

qPCR offers a linear dynamic range of detection - from as little as ten to as many as several hundred million copies of a pathogen in a sample. Both amplification and detection occur in a single reaction, eliminating post-PCR manipulations, reducing testing time to hours instead of days.

Fluorescence chemistry-based methods have revolutionized molecular diagnostics, with quantitative PCR (qPCR) being heralded as the new "gold standard" for viral load quantification and detection of bacterial, fungal and viral pathogens.

The **CUUR Diagnostics** qPCR panel assays are based on 5' nuclease chemistry, which uses a fluorogenic probe to enable the detection of a target-specific PCR product as it accumulates during PCR.

Each individual assay contains a pair of unlabeled primers, a probe with a FAM™ or VIC™ dye label on the 5' end, and a minor groove binder (MGB) and nonfluorescent quencher (NFQ) on the 3' end.The figure below depicts the amplification process into steps.



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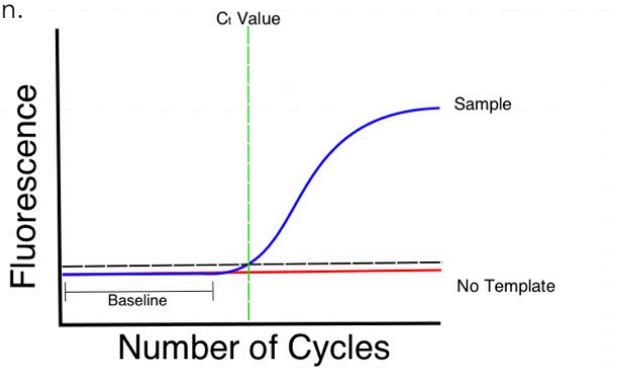
Advantages of Quantitative PCR (qPCR) -Based Infectious Disease Testing and Diagnostics

With each cycle of qPCR, more dye molecules are released, resulting in an increase in fluorescence intensity proportional to the amount of amplicon synthesized. With qPCR, the nucleic acid is amplified until it produces a detectable, above background level of fluorescent signal. As defined as the fractional cycle number at which the fluorescence passes the background, the cycle threshold (Ct) is used to calculate the number of target molecules originally present based on a standard curve.

Factors that Can Influence Ct

Ct (cycle threshold) is the intersection between an amplification curve and a threshold line (see below). It is a relative measure of the concentration of target in the PCR reaction.



Targets are detected in real time without post-PCR processing being required, nearly eliminating the risk of false-positive results due to amplicon carryover.

Culture
- Involves high level of trial and error
- Lengthy waiting periods
- Potential to fail to identify organisms
- Requires costly lab time
- Analysis is affected by current antibiotic use

qPCR
- Highest level of sensitivity and specificity
- Can be completed in 24-hours
- Simultaneously identifies viruses, bacteria, parasites, and fungi
- Provides a more definitive diagnosis
- Current antibiotic use does not affect results

Considering the clinical importance of Infectious Disease, the significant number of infected worldwide and the serious health consequences to our population, it's clear why extremely precise, rapid, and sensitive qPCR has been identified as the new "gold standard" for Infectious Disease Diagnostics.

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INFECTIOUS DISEASE DIAGNOSTICS

Advantages of Quantitative PCR (qPCR) -Based Infectious Disease Testing and Diagnostics

Improving Patient Outcomes with qPCR

For decades, infectious diseases have caused significant public health and financial challenges. Traditionally, routine lab testing for infectious agents is performed with culture-based methods, which have a low sensitivity and specificity and can take days to get results.

Infectious Diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites, or fungi, which can directly or indirectly spread from one person to another. The impact of these pathologies is evidenced by:

- High numbers of individuals impacted by Infectious Disease
- Lack of knowledge about the infectious agents
- Global socioeconomic impact of Infectious Disease
- Advent of Antimicrobial Resistance
- Increase in molecular diagnostic research for Infectious Disease
- Rapid developments of diagnostic techniques for the early detection
- Emergence of new infectious diseases
- Reemergence of diseases once controlled
- Development of Diagnostic and Antimicrobial Stewardship

Long turn-around times to detect pathogens by conventional culture methods is insufficient to rapidly diagnose infectious diseases. Not all pathogens are cultivable and may require discernment of species, virulence factors, and anti-microbial resistance to be effective. In contrast, the amplification techniques in molecular testing can be used for detection, genotyping, and quantification of virus and bacteria in various clinical specimen types.

qPCR: Rapid Results with Extreme Specificity to Improve Patient Outcomes

Molecular diagnostics can identify a wide range of microorganisms. Due to its incredible sensitivity, specificity, reproducibility, broad dynamic range, and speed of amplification qPCR has been championed by infectious disease experts for identifying organisms that cannot be grown in vitro or where existing culture techniques are insensitive or require prolonged incubation times. Advances in development of molecular technology and diagnostics have enhanced understanding Infectious Disease etiology, pathogenesis, and molecular epidemiology. Molecular diagnostics provide a basis for quantification, appropriate detection, prevention, and control measures by which some diseases have been successfully eliminated.

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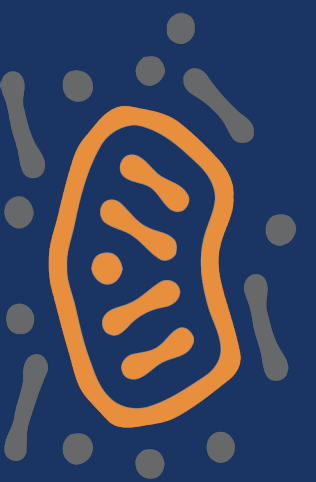

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