GeneSTAT
RAPID DNA TESTING

d/b/a

Genetec
TESTING & DEVELOPMENT

Technology Overview

January 2020

Genetec by GeneSTATMDx: A Differentiated Approach

Genetec develops and manufactures high value qPCR molecular diagnostic instruments/platforms and unique tests with a focus in the area of infectious disease diagnosis and screening

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Clinical Diagnostic & Screening Products Overview

Current System

GeneSTAT System

- GeneSTAT System is a patented closed *in vitro* diagnostic assay platform
- Discreet, on demand, 24/7 testing capability
- A POCT platform that uniquely targets near to patient tests for specific infectious disease for differential diagnosis in diverse environments
- Requires minimal maintenance and no calibration

Test Cartridges

- Patented single use cartridge contains all necessary reagents for detecting DNA/RNA targets
- Closed system, built in containment, allows diverse environment operation
- Internal Control verifies multiple aspects of test conditions and assay of every sample tested

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The GMD advantage

- ✓ **Simply, a Unique Platform and Better Tests:**
  - GeneSTAT®, a Unique & Disruptive test technology focused on infectious disease agents and antibiotic resistance
  - A POCT platform that uniquely targets near to patient tests for specific infectious disease for differential diagnosis which for the most part are not addressed by other molecular diagnostics (MDx) companies
- ✓ **Well Positioned versus Competition:**
  - GeneSTAT Platform US FDA cleared
  - Our Innovative system provides 24/7 rapid ID results allowing clinicians to optimize treatment
  - The first FDA cleared rapid molecular test for Valley Fever
  - Recent external studies published in peer reviewed journal prove speed and potential clinical value of GeneSTAT tests
  - DxNA's unique MRSA+ test: No current comparable analysis for this critical healthcare challenge
  - Compelling pipeline of tests
  - Translational Genomics Research Institute relationship
  - Simple and low cost of goods consumable compared to most (if not all) sample to result molecular testing systems

The DxNA GeneSTAT Value Advantage

- ✓ **Recent Studies Prove our System:**
  - GeneSTAT/Assay Performance: Peer reviewed journal, FDA clearance
  - Robustness of instrument and assay design/development capabilities
  - Improved lab workflow
  - Well positioned competitively
- ✓ **Verified performance & robustness = US FDA clearance**
- **Risk analysis = verified design**
- Sensitivity 100%; Specificity 99.6%
- Precision Repeatability – 87.5% - 100%
- Reproducibility: multiple GeneSTATs, cartridge lots and technologists – 100% across all
- LOD studies – 10 GEq/ml
- Micro-organism Interference - None
- Cross Reactivity – None = robust probe & primer design
- Interfering substances - None
- Carryover Cross Contamination – None, by design
- Shelf life – up to 18 months at ambient temperature
- Firmware/Software trace verified as per FDA requirements
- External Multicenter blinded study proves GeneSTAT system performance

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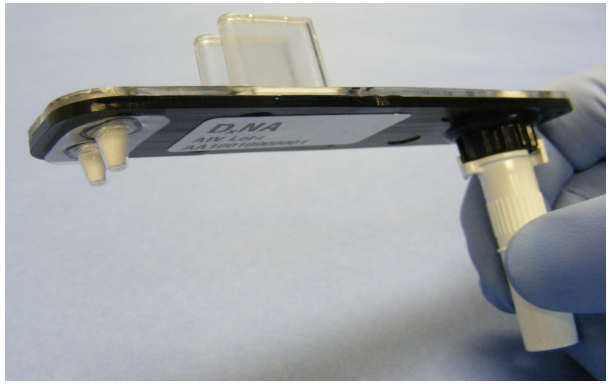
The DxNA System: GeneSTAT® Cartridge Key Features

Each cartridge is a self-contained assay system

- Two reaction wells, each with 2-plex =3 analytical targets + 1 control
- Computer chip in the label identifies the test and testing parameters
- Containment in a closed-system cartridge
- No sample-to-sample carryover, complete biological containment
- Cartridge internal quality control verifies multiple aspects of each assay run.
- Simple and low cost of goods consumable compared to most (if not all) sample to result molecular testing systems



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The GeneSTAT Value Proposition Summary

- ✓ Performance: Recent internal and external studies prove laboratory value and potential clinical value
- ✓ Ease of Use: minimal expertise to operate with 24/7 actionable results
- ✓ Speed: Test time and minimal hands on time
- ✓ Economical: Low consumable cost provides pricing flexibility
- ✓ Reliability: Rugged with minimal maintenance

- ✓ US FDA regulatory clearance
- ✓ Well Positioned versus Competition:
- ✓ Compelling Pipeline of additional tests

GeneSTAT.MDx™ Coccidioides Test (Valley Fever)

Simply, a Better Test™

The Problem

Improved outcomes escape us largely due to diagnostic shortcomings

- Increasing incidence of Valley Fever (coccidioidomycosis)
- No rapid, FDA-cleared molecular diagnostic prior to DxNA-November 2017
- Average time to diagnosis is 5 months[1] from seeking healthcare
- Up to 30% of Community Acquired Pneumonia (CAP) cases in the U.S. Southwest are misdiagnosed and are actually Valley Fever infections.[2] Due to shortcomings in available diagnostic methods most Valley Fever cases are missed or misdiagnosed.[4]
- Misdiagnosis leads to:
  - Inappropriate and ineffective antibiotic use
  - More severe disease, leading to increased morbidity and mortality
  - Increased patient suffering
- Average cost of hospital care alone is $50,000 per hospitalization [3]
- Testing and culturing *Coccidioides* puts lab personnel at risk and requires Biosafety Level 3 lab

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GeneSTAT.MDx™ Coccidioides Test

Simply, a Better Test™

The Solution

Recent external studies prove our test is fast and accurate

- Closed-system, cartridge-based assay
- Testing direct from specimen, no culture required
- Provides results in less than 1.5 hours after DNA extraction
- Clinical Agreement DxNA vs. Fungal Culture/DNA Probe:
  - Retrospective Sample Sensitivity 100% (51/51)
  - Prospective Sample Specificity 99.6% (227/228)
- Detects All *Coccidioides* strains

The Solution Value

Reduces diagnostic uncertainty for improved patient outcomes

- Can provide for earlier disease intervention with appropriate therapy [4]
- Improves patient outcomes and lowers treatment costs [4]
- Reduces morbidity, mortality, patient suffering, lost productivity and healthcare costs [4]

The first FDA cleared rapid molecular test to market, which provides a much-needed definitive solution for this $35 - $60 million per year niche market.

Note: Cocci references 1- 5 on file

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Staphylococcus Diagnostic & Screening Assays

MRSA⁺ Simply, a Better Test™

The Problem

Antibiotic Resistance contributes to considerable mortality and morbidity

- Staphylococcus aureus (SA), and Coagulase Negative Staphylococcus (CoNS) and their resistant strains are the most common pathogens in Surgical Site Infections (SSIs) (ACS & CDC)
- Hospital Acquired Infections, (HAIs) are an increasing global problem
- (SSIs) are increasing due to additional use of biomaterials[6]; SA & CoNS together are the second most common HAI and in the U.S., the most expensive to treat; up to $90K per infection in orthopedics, and $10B total annually
- Studies in orthopedic surgery infections have shown that the antibiotic selected for prophylaxis was inappropriate for 60% plus of cases for the causative strain of infection [5]
- ***There is currently no rapid molecular test for diagnostics or screening that can identify and differentiate resistant and non-resistant SA and CoNS, either alone or in specimens containing multiple strains***

Note: Cocci references 1- 5 on file

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Staphylococcus Diagnostic & Screening Assays

MRSA+ Simply, a Better Test™

The Solution

GeneSTAT MRSA+ ID's & differentiates SA, CoNS & mec A, the Gene conferring resistance

- DxNA has developed the MRSA+ Assay through Beta testing. It is the only molecular assay that identifies and differentiates SA and CoNS resistant and non-resistant strains, including specimens containing multiple strains
- The assay when implemented on the GeneSTAT System provides rapid, close to patient testing, facilitating pre-surgical testing at all surgery locations
- The assay can also be configured for use on other laboratory-based PCR platforms

The Value

Rapid ID and actionable results enable clinicians to optimize therapy earlier

- Screening and decolonization of methicillin resistant Staphylococcus decreases the incidence of postoperative SSIs in orthopedic patients [7]
- Identification and differentiation of resistant and non-resistant Staphylococcus strains provides rapid guidance to the clinician for optimal antibiotic selection for treatment of active infections
- Identification of Staphylococcus strains facilitates appropriate antibiotic selection reducing incidence of SSIs, costs and mortality associated with them while improving patient outcomes [2,5,6,7]
- No current comparable differential analysis for this critical healthcare challenge in this large and growing market opportunity (>$1.8B)

Note: MRSA references 1- 11 on file

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Staphylococcus Diagnostic & Screening Assays

MRSA⁺ Simply, a Better Test™

The Competition

- There currently is no rapid or molecular Screening/Diagnostic test that can ID and differentiate drug resistant forms of *Staphylococcus Aureus and Coagulase Negative Staphylococcus*
- Current tests completely ignore Coagulase Negative Staphylococcus (CoNS). Even though CoNS is the most common Staphylococcus pathogen accounting for 30-50% of Staph infections
- Current tests do not provide physicians and surgeons a way to rapidly identify and differentiate the different resistant and non-resistant strains in order to deliver the most effective and appropriate therapy to treat or prevent the infections expeditiously and cost effectively
- Current assays for MRSA have issues with false positives and false negatives [10,11]

Note: MRSA references 1- 11 on file

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Staphylococcus Diagnostic & Screening Assays

MRSA+ Simply, a Better Test™

Diagnostic Test Market:

- There are 780,000 SSIs[1] in the US and 900,000 SSIs in the EU each year.[3,4] At a test price of $49, this is an ***$82 million/year diagnostic market opportunity in the US & EU. US & EU account for 80% of the molecular diagnostics market***
- In the US, infections occurring 30 days or more after surgery are not considered in the SSI or HAI numbers. This represents an additional diagnostic market opportunity
- Rest of World SSI rates are considered to be equal to or higher than rates in the developed world, however the opportunity for testing is lower

Screening Test Market:

- There are 20,000,000 surgical procedures each year in the US[1]and 12,000,000 surgical procedures in the EU[3]. At a test price of $49 this is a ***$1.56 billion/year screening market opportunity (US & EU)***

- **DxNA's MRSA+ Screening and Diagnostic tests address, in a novel and differentiated way, a large and growing market opportunity (>$1.7B)**

Note: MRSA references 1- 11 on file

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Intellectual Property Portfolio

- **Patents**
  - 6 issued U.S. patents
  - 1 pending U.S. patent
  - 10 issued foreign patents – China & Europe
  - 5 pending foreign patents
  - 2 diagnostic licenses of granted patents (TGen) – Valley Fever, MRSA+
  - 1 food purity content of granted license (UPM) – Hafys™ Halal

- **Trademarks**
  - GeneSTAT®
  - GeneSTAT.MDx™
  - GeneSTAT.Inspect™
  - PathoGene ® (Service Mark)
  - PCReports ™

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GeneSTAT® Cartridge Manufacturing

GMD manufactures its unique cartridge in its Class 7 clean room using equipment custom designed for the assembly of its test cartridges

- Current capacity of 50,000+ cartridges per month
- Meets projected requirements into 2022

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