Alere: Meeting the Growing Demands

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(Formerly Director of New Product Development)
Global leader in near-patient diagnostics with annual revenues in excess of $2.5B.

Global leader in near-patient diagnostics for the most prevalent infectious diseases.

We have several novel platforms launched or launching soon that will sustain this position well into the future:

- Alere™ CD4 Analyzer… PIMA – provides absolute CD4 results to initiate and help manage antiretroviral therapy.
- Alere™ iNAT – molecular platform for acute near-patient testing. First application expected in time for the 2013 – 14 US flu season.
- Alere™ qNAT – HIV viral load testing, with applications for HCV and TB in development. Studies to support regulatory clearances currently underway in Africa.
ALERE’S MISSION

To empower individuals with the freedom to gain greater control over their own health, under the supervision of their healthcare providers.

RESULTS:
- Earlier interventions
- Personalized treatment
- Fewer hospitalizations
- Reduced healthcare costs
- Better quality of life
HIV Treatment Cascade

Out of the more than one million Americans with HIV:

- 902,000 know they are infected (82%)
- 726,000 were linked to HIV care (66%)
- 407,000 have stayed in HIV care (37%)
- 363,000 are receiving treatment (33%)
- 275,000 have a very low amount of virus in their bodies (25%)

US HIV Treatment Cascade

Graph data from US CDC 2010

Alere Determine Combo
Rapid POC HIV testing
Earlier case ID

Alere CD4
Increasing access to care
Loss to patient follow-up
Knowing your #’s

Alere q HIV Viral Load
Knowing your #’s
Care Management
US HIV Treatment Cascade

Graph data from US CDC 2010

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Rapid POC HIV testing
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Graph data from US CDC 2010
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US HIV Treatment Cascade

Alere CD4
Alere q HIV Viral Load
Knowing your #'s

In Development
US HIV Treatment Cascade

Graph data from US CDC 2010

- HIV Infected: 1,178,350
- HIV Diagnosed: 902,000
- Linked to Care: 726,000
- Retained in HIV Care: 407,000
- On ART: 363,000
- Suppressed Viral Load (≤200 copies/mL): 275,000

Alere q HIV Viral Load Care Management

In Development
US HIV Treatment Cascade

Alere q HIV Viral Load

Graph data from US CDC 2010
# Capability & Capacity: Meeting the Growing Demands

<table>
<thead>
<tr>
<th>Issues</th>
<th>Comments</th>
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| 1. Sustainable Solutions                                     | • Requires significant resources.  
  ○ Scale Up, Training, Supply logistics, Validation of new technologies.  
  ○ Larger companies have the resources but often the time horizons for return on investment are misaligned with market realities, especially in the developing world.  
  ○ Smaller companies struggle with this.                                                                         |
| 2. Complexity of Regulatory Processes and Duplication of Validation Procedures. | • Requirements are variable and often specific to each individual country.  
  ○ There exists significant duplication of validation processes in the developing world.                            |
| 3. Pricing                                                    | • Massive downward pressure on pricing, due in part, the large scale tender in HIV screening in the dev. world. (Global Fund, US gov., Etc.)  
  ○ Numerous cases where huge tenders were filled at a loss.                                                       |
Alere Infectious Disease POC Diagnostics
END… Tour of Britain
Back Up Slides
# Alere Determine™ Combo

## Product Information

<table>
<thead>
<tr>
<th>Information Type</th>
<th>Product Detail</th>
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</thead>
<tbody>
<tr>
<td>Method</td>
<td>Lateral flow</td>
</tr>
<tr>
<td>Time to results</td>
<td>20 minutes</td>
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<tr>
<td>Results window</td>
<td>20-30 minutes after starting test</td>
</tr>
<tr>
<td>Test lines</td>
<td>HIV-1 p24 antigen</td>
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<tr>
<td></td>
<td>HIV-1/2 antibodies</td>
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<td>Storage conditions</td>
<td>2-30 °C (36-86 °F)</td>
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<td>Test shelf life</td>
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<tr>
<td>Sample type</td>
<td>Whole blood/serum/plasma</td>
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- Approved for Moderate Complexity
- Conducting CLIA Waiver Studies

![Image of test strip with labels: Control, p24 Antigen, Antibodies, Sample pad]
Alere™ CD4 Analyzer

- The world’s first point-of-care CD4 Analyzer
- Results <20 minutes
- No External calibration
- On-board data archive
- Disposable cartridge
- Dried reagents
- “Connectivity”
Alere™ q HIV-1/2 (In Development)

- The world’s first point-of-care viral load assay for HIV-1 and HIV-2
- Viral load monitoring and molecular HIV diagnosis
- Exquisite Quantification
- “Connectivity”
- Currently in development.
Alere HIV Portfolio: Roadmap

Covering the full spectrum from prevention & wellness to diagnosis, staging, monitoring therapy and disease progression

**Prevention**

**TESTING**

**PREVENTION & DIAGNOSIS**
Includes Health & Wellness, education, HIV Pre-exposure Prophylaxis (PrEP), screening, Early (acute) case detection

**STAGING**

**Disease & immune system staging for therapy initiation**

**Monitoring / Management / Care & Wellness**

**TESTING**

**STAGING**

**MONITORING**
Management, optimization of therapies, Rx resistance indicators (genotyping/phenotyping), palliative care throughout care continuum

**THERAPY (Lifelong)**

**CO-MORBIDITIES**
Screening for co-morbidities, complications, opportunistic infections. Include, but not limited to, respiratory, gastro-intestinal, STDs, cardiovascular and cancers

All Platforms (CD4, Alere q, Alere i) to deploy with connectivity and relevant Informatics/Data Management
Changing Perception

Sensitivity of assay reactivity during early HIV-1 infections relative to number of days before first positive Western Blot

**Alere Determine™ HIV-1/2 Ag/Ab Combo**
15.5 days before Western Blot positive

**AVERAGE DAYS BEFORE POSITIVE WESTERN BLOT**
- NAT
- 4th gen IA
- 3rd gen IA
- Conventional antibody only rapid tests
HIV Infection & Laboratory Markers

- Appearance of markers for HIV infection vary over time
- Viral RNA is first detectable marker
- Antibodies do not appear during early infection
- Antigen appears early (alone) and later complexed with antibodies
HIV/AIDS: Global Trends

• Globally, ~34.0 million people were living with HIV at the end of 2011.
  o Globally, the number of HIV+ individuals are expected to grow from 34M to 47M by 2020
  o Sub-Saharan Africa remains most severely affected, with nearly 1 in every 20 adults (4.9%) living with HIV and accounting for 69% of the people living with HIV worldwide.
  o ~5 million people are living with HIV in South, South-East and East Asia combined.
  o ~2.5M people are newly infected each year (declining)

• Antiretroviral therapy Guidelines updated by WHO (July 2013)
  o Currently 9.7M people on ART of 16.7M that would qualify – CD4 count <350 (2010 guidelines)
  o 2013 WHO Guidelines increased initiation threshold to a CD4 count of 500 = 25.9M now eligible for ART

• Acute HIV identification becoming increasingly important. Identifying persons with acute HIV infection is viewed as an effective HIV prevention strategy.

• Significant increase in HIV testing is expected due to availability of pre-exposure prophylaxis (PrEP) prevention interventions
  o TRUVADA received FDA Advisory Panel approval for use in PrEP in 2012.
  o The need for effective HIV-1 prevention has never been greater
HIV/AIDS: United States Trends

• Goals of the US National HIV/AIDS Strategy
  - Reducing New HIV infections ...(by 2015):
    ▪ Lower the annual number of new infections by 25%
    ▪ Reduce the HIV transmission rate by 30%
    ▪ Increase the % of people living with HIV who know their serostatus from 79% to 90%
  - Increasing Access to Care & Improving Health Outcomes for People Living with HIV… (by 2015):
    ▪ Increase the proportion of newly diagnosed patients linked to clinical care within three months of their HIV diagnosis from 65% to 85%
    ▪ Increase the proportion of Ryan White HIV/AIDS Program clients who are in continuous care from 73% to 80%
  - Reducing HIV-Related Health Disparities … (by 2015):
    ▪ Improve access to prevention and care services for all Americans
    ▪ By 2015, Increase the proportion of HIV diagnosed gay and bisexual men, Blacks and Latinos with undetectable viral load by 20%

• Loss to follow-up is one of the largest challenges to the US HIV care system
  - This can occur at any one of the steps across a continuum of care

• According to the US CDC*, only 28% of all persons living with HIV infection in the US are virally suppressed (some studies put this as low as 15%)

• In the latest version of the US DHHS Guidelines…“Regardless of CD4 count, initiation of ART is strongly recommended…”
  - However, most KOLs will continue to use CD4 in disease staging and as a surrogate marker of disease progression.

• The recently released study findings of HPTN 052 demonstrated a 96% reduction in HIV transmission among serodiscordant couples attributable to viral load suppression
  - These findings have additional evidence support for the treatment as prevention paradigm

* MMWR: Dec. 2, 2012