

The Current Evolution of Diagnostic Testing in Pharmacies and Physician Offices and Companion Diagnostics

January 27, 2016



Disclosures

- Jack Kain, PharmD: Clinical Toxicologist and Pharmacogenomic Specialist at Precision Diagnostics
- Precision Diagnostics has no affiliations or financial incentives with any products and their respective companies discussed within this presentation



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Overview

- What is In Vitro Diagnostics (IVD)?
- What is Happening in the IVD Industry?
- Personalized Medicine – Companion Diagnostics
- An Evolution in Point of Care In Vitro Diagnostics (IVD) and Community Pharmacy Practice

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What is In Vitro Diagnostics (IVD)?

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What is In Vitro Diagnostics?

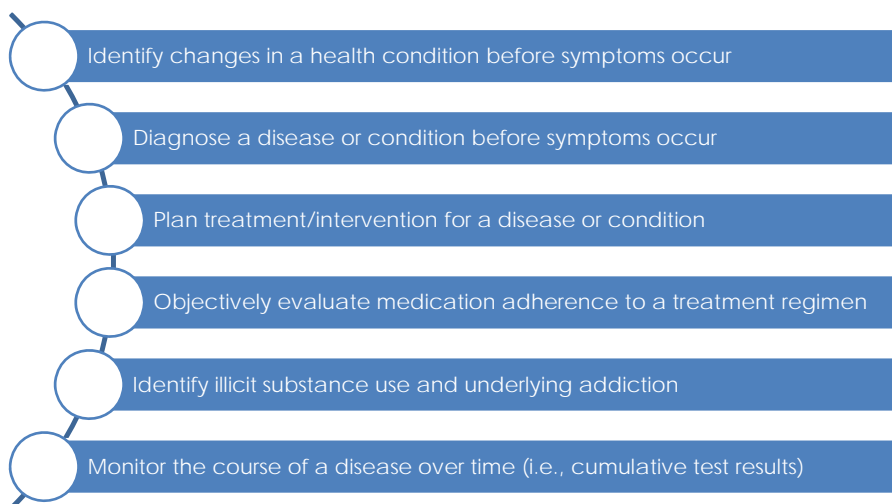
- Products intended for assessing medication adherence and/or use in diagnosis of disease or other conditions, including a determination of the state of health in order to cure, mitigate, treat or prevent disease or sequelae.
- Products utilized in the collection, preparation and examination of specimens taken from the human body.
- Information obtained from laboratory test results must be interpreted within the context of a patient's overall health. Test results are one objective piece of the entire clinical picture of the patient.

Personalized Medicine and Companion Diagnostics Go Hand-in-Hand. FDA. 2014.
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm407328.htm>. Accessed January 18, 2016.

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Clinicians use IVD Products and Services to?



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What is Driving the IVD Market?

- Improve patient outcomes
- Reduce overall costs on healthcare system

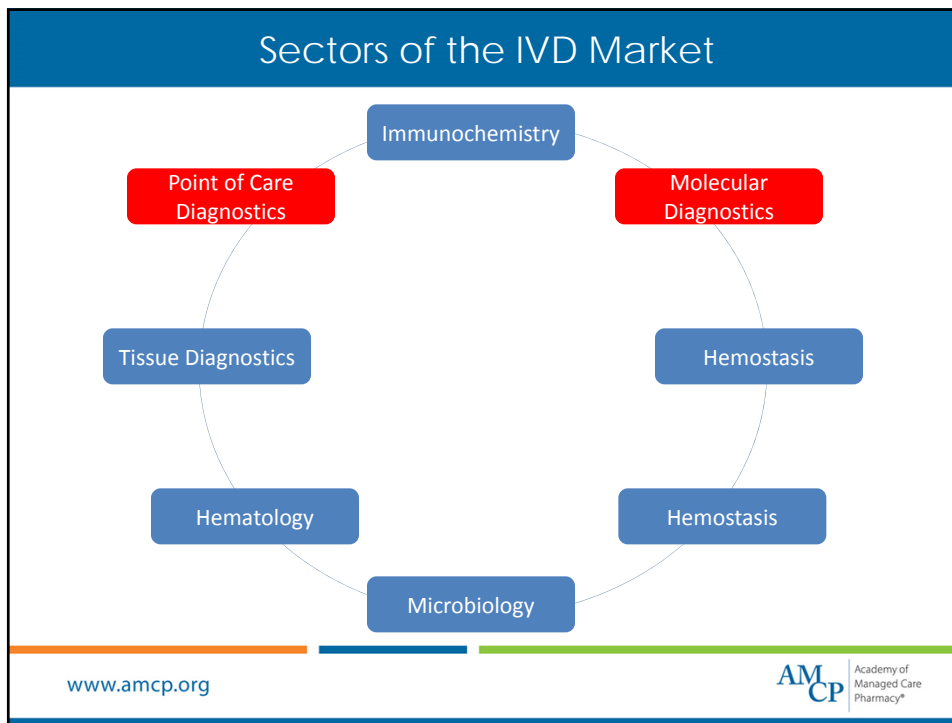
- More efficiently diagnose disease
- Reduce adverse events before they occur

A Healthy Prognosis for the IVD Market. Medical Product Outsourcing, 2014. http://www.mpo-mag.com/issues/2014-11-01/view_features/a-healthy-prognosis-for-the-ivd-market. Accessed January 24, 2016

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What is Happening in the IVD Industry?

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Largest Growing Sectors of IVD Market

- The United States is the largest IVD market in the world, with an estimated \$24.1 billion in annual revenues. (Kalorama Report)
- Five sectors of IVD anticipated to have the largest growth through 2018 ($\geq 5\%$ growth):
 - Histology
 - Molecular Diagnostics (i.e., Personalized Medicine)
 - Point of Care Diagnostics (i.e., Point of Care Testing, Point of Collection)
 - Microbiology
 - Virology

IVD Market Moving Rapidly on an Upward Trajectory. GEN. 2012. <http://www.genengnews.com/gen-articles/ivd-market-moving-rapidly-on-an-upward-trajectory/4620/>. Accessed January 20, 2016.

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Personalized Medicine Companion Diagnostics

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Molecular Diagnostics

- Molecular diagnostics encompasses many different assays including those for non-infectious diseases (i.e., neonatal, prenatal screening, companion diagnostics) and infectious diseases (i.e., hospital acquired infections, urinary tract infections)
- A specialized area of molecular diagnostics that is projected to have substantial global growth (~\$8.7 billion) through 2019 is the **Pharmacodiagnosics - Companion Diagnostics Market**
- This growth is largely the result of our new understanding of the human genome and its implications on drug therapy and the personalized medicine movement

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Brief History of Personalized Medicine

1959

"Pharmacogenetics" was first coined by Vogel when describing issues in human genetics

1962

The first pharmacogenetics textbook, *Pharmacogenetics: heredity and the Response to Drugs* was published in 1962.

1977


Discovery of the cytochrome P450 enzyme system and its ability to bio-transform drugs

2003

Completion of the human genome project catalyzes personalized medicine

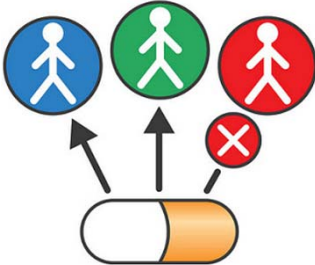
The case for Personalized Medicine. Personalized Medicine Coalition. 2014.
http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_case_for_personalized_medicine.pdf

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What is Personalized Medicine?

- The ability to identify molecular biomarkers that signal disease risk or presence before signs and symptoms manifest.
- Focused on early intervention or prevention rather than a trial and error approach to treating advanced stages of a disease
- Direct optimal therapy for a patient the first time (i.e., precision medicine)
- Mitigating the costly practice (for all stake holders) of trial and error prescribing



The case for Personalized Medicine. Personalized Medicine Coalition. 2014.
http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_case_for_personalized_medicine.pdf

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The Era of Personalized Medicine

- The FDA's acknowledgement and focus on personalized medicine has been signaled by the creation of a **Director for Personalized Medicine in the Office of In Vitro Diagnostics and Radiological Health**
- The release of its report *Paving the Way for Personalized Medicine: FDA's role in a New Era of Medical Product Development* describes many of the developments and impending advances in personalized medicine.
- In 2011, the FDA released its *Draft Guidance for In Vitro Companion Diagnostic Devices*
 - Clarified FDA's intentions to conduct simultaneous reviews of a drug and its corresponding diagnostic test.

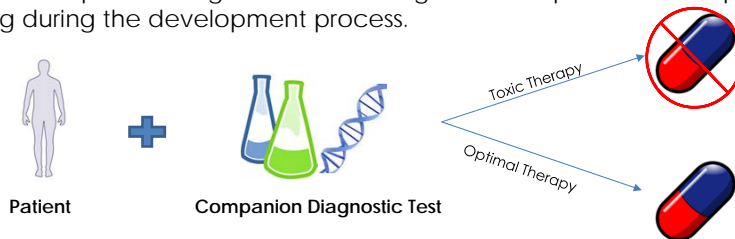
The case for Personalized Medicine. Personalized Medicine Coalition. 2014.
http://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/pmc_case_for_personalized_medicine.pdf

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What is Companion Diagnostics?

- Medical devices that provide information that is essential for the safe and effective use of a corresponding therapeutic agent or biological product.
 - For example, a companion diagnostic test is required if a new drug works on a specific genetic biomarker or biological target that is present in only in a subset population of patients (i.e., cancer patients)
- Each companion diagnostic test is designed to be paired with a specific drug during the development process.



Personalized Medicine and Companion Diagnostics Go Hand-in-Hand. FDA. 2014.
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm407328.htm>. Accessed January 18, 2016.


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2006 Examples of Drug/Companion Diagnostics Combinations

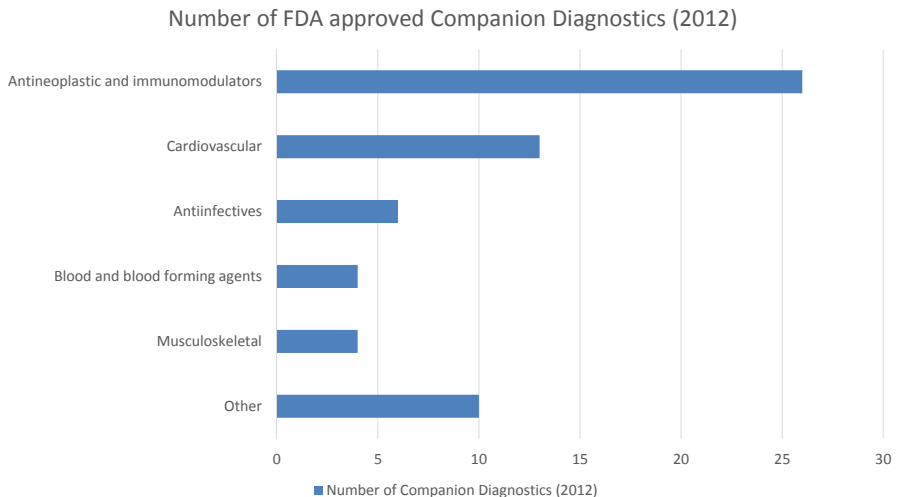
- Many cancer focused companion diagnostics have already been successfully implemented into routine diagnostic and tailored treatment plans.
- The number of companion diagnostics on the market has grown rapidly. In 2006, there were 5 drug/diagnostic combinations that met the FDA definition of a companion diagnostic all indicated for oncology.
 1. irinotecan (Camptosar[®]) and Invader[®] UGT1A1 Molecular assay
 2. imatinib mesylate (Gleevec[®]) and BCR-ABL LDT and DAKO C-Kit PharmDx[®] for gastrointestinal stromal tumors (GIST)
 3. trastuzumab (Herceptin[®]) and DAKO Herceptest[®]
 4. mercaptopurine (Purienthol[®]) and laboratory-developed thiopurine methyltransferase test
 5. tamoxifen (Novaldex[®]) and laboratory-developed estrogen receptor test

Agarwal A, Ressler D, Snyder G. The Current and Future State of Companion Diagnostics. Pharmacogenomics Pers Med. 8: 99 – 110. 2015.

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Multiple Types of Companion Diagnostics

Number of FDA approved Companion Diagnostics (2012)



Therapeutic Category	Number of Companion Diagnostics (2012)
Antineoplastic and immunomodulators	26
Cardiovascular	13
Antiinfectives	6
Blood and blood forming agents	4
Musculoskeletal	4
Other	10

Agarwal A, Ressler D, Snyder G. The Current and Future State of Companion Diagnostics. Pharmacogenomics Pers Med. 8: 99 – 110. 2015.

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trastuzumab (Herceptin[®])

- Companion diagnostics began in 1998 with the FDA approval of Herceptin[®].
- Herceptin[®] is a monoclonal antibody which binds to human epidermal growth factor receptor 2 protein (HER-2). HER2 is a protein found in high concentrations of aggressive types of breast cancers (~ 30%)
- The companion diagnostic test (i.e., PathVysion HER-2 DNA Probe Kit[®], HercepTest[®]) looks for high levels of HER2 in a patient's tumor indicating that Herceptin[®] could be an effective treatment for that patient's breast cancer.

Personalized Medicine and Companion Diagnostics Go Hand-in-Hand. FDA. 2014.
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm407328.htm>. Accessed January 18, 2016.

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Example: panitumumab (Vectibix[®])

- Recently the FDA approved a companion diagnostic genetic test to select patients with metastatic colorectal cancer for treatment with panitumumab (Vectibix[®]).
 - The test detects seven mutations in the Kras gene within colorectal tumor tissue.
 - Mutations in the Kras gene have been implicated with rendering Vectibix an inefficient treatment for colon cancer.
 - A patient without a mutation in the Kras gene would be a good candidate for this treatment.
- ~40% of patients with metastatic colon cancer are unlikely to respond to cetuximab (Erbix[®]) and panitumumab (Vectibix[®]) because their tumors have mutated a form of KRAS gene.
- Guidelines recommend that only patients with the normal (wild-type) form of KRAS gene should be treated with these drugs in conjunction with chemotherapy

Personalized Medicine and Companion Diagnostics Go Hand-in-Hand. FDA. 2014.
<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm407328.htm>. Accessed January 18, 2016.

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Important Role of Payers and Reimbursement

- Insurers and clinicians are very much interested in obtaining objective information on an expensive medication's potential efficacy and the likelihood of significant adverse events per patient.
- The standard course of chemotherapy can cost an upwards of \$100,000 per patient and result in severe adverse effects that lead to increased ER visits and costs incurred on health plans.
- There are now several examples of personalized medicine that have been adopted in clinical practice and covered by health plans.
- One example has been seen with the widespread adoption and commercialization of Genomic Health's Oncotype DX[®] for breast cancer.
 - Genomic Health's Oncotype Dx[®]: Price tag of \$4,290 has not hindered acceptance with payers
 - > 90% of US lives covered

Trosman JR, Van Bebber SL, et al., Coverage Policy Development for Personalized Medicine: Private Payer Perspectives on Developing Policy for the 21-Gene Assay. *Journal of Oncology Practice*. 6. 238 – 242. September 2010.

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Example: Adoption of OncotypeDx[®] Test

- The Trial Assigning Individualized Options for Treatment Rx (TAILORx) Breast Cancer Trial using Oncotype DX[®]
 - Initial findings show that women with early-stage hormone receptor-positive breast cancer that have a **low risk of recurrence score** have very low 5-year recurrence rates when post-operative treatment consists of **hormone therapy alone (i.e., tamoxifen)**.
- The test categorizes a recurrence risk score into **1) low, 2) intermediate or 3) high**.
 - Patients with **low** recurrence scores are **less likely to relapse** and **less likely to benefit from chemotherapy**
 - **High** recurrence scores indicate **higher probability of relapse** and **higher likelihood of chemotherapy benefit**
 - Treatment decisions may not change for patients with intermediate recurrence scores

Sparano JA, Gray RJ, et al. Prospective Validation of a 21-Gene Expression Assay in Breast Cancer. *N Engl J Med* 2015. 373. 2005 - 2014

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Key Factors for Adoption of a Companion Diagnostic Device as Mentioned Managed Care Organizations

- **Clinical Effectiveness** (i.e., retrospective or prospective studies, randomized controlled trials, literature)
- **Health outcomes evidence** (i.e., impact on patient disease and survival)
- **Evidence that the test affects clinical decisions** (i.e., changing/directing physician recommendations)
- **Endorsements from medical societies**
- **Initial coverage by state Medicare or other health plans**
- **Physician/clinician adoption** (i.e., widespread acceptance by providers)

Trosman JR, Van Bebber SL, et al. Coverage Policy Development for Personalized Medicine: Private Payer Perspectives on Developing Policy for the 21-Gene Assay. *Journal of Oncology Practice*. 6. 238 – 242. September 2010.

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Future of Companion Diagnostics and Personalized Medicine

- Future growth of companion diagnostics will rely on continued collaboration between all stake holders (i.e., patients, providers, payers, laboratories, drug developers)
- Payers highly desire diagnostic tests that provide information on multiple treatment options within a therapeutic area as opposed to the current model of a single diagnostic test tied to a single pharmaceutical agent.
- Drug developers can continue to experience economic benefits by achieving faster to market time with less expensive clinical trials for drugs with significant revenue potential
- New and more convenient specimen collection models to increase patient convenience and turnaround time.
- Healthcare reform is pushing clinical provider payments based on patient outcomes and less emphasis on the number and type of interventions. This underlies the tremendous upside/demand of choosing the optimal drug based on companion diagnostic testing.

IVD Market Moving Rapidly on an Upward Trajectory. GEN. 2012. <http://www.genengnews.com/gen-articles/ivd-market-moving-rapidly-on-an-upward-trajectory/4620/>. Accessed January 20, 2016.

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An Evolution in Point of Care In Vitro Diagnostics (IVD) and Community Pharmacy Practice

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The Laboratory – Pharmacy Partnership

- Laboratory companies have known that partnering with clinicians can improve the quality of their products while simultaneously improving patient outcomes.
- Innovative laboratories are beginning to understand the pharmacist's expertise in pharmacotherapy and the value they can bring to the efficacy of lab tests and drug therapy
- The laboratory is becoming less isolated and more integrated into clinical decision support systems (CDSS) and the patient care process by teaming up with physicians, pharmacists and managed care entities.

The Emergence of Lab-Pharmacy Partnerships. AACC. 2012. <https://www.aacc.org/publications/clin/articles/2012/may/lab-pharmacy-partnerships>. Accessed January 20, 2016.

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Why the Pharmacy?


- 92% of Americans live within 1.6 miles of a pharmacy
- Evolution of Pharmacy from dispensing and merchandising model to a pseudo-primary care model
- Pharmacies can generate another source of revenue while simultaneously improving patient outcomes
- Pharmacists have a particular skill set in medication management, therapeutic drug monitoring and medication adherence monitoring

Adequacy of Pharmacist Supply:2004 to 2030. Department of HHS. 2008.
<http://bhpr.hrsa.gov/healthworkforce/reports/pharmsupply20042030.pdf>. Accessed January 21, 2016.

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Two Primary IVD-Pharmacy Business Models



Point of Collection Model


- Pharmacogenomics
- Medication adherence monitoring
- Therapeutic drug monitoring (TDM)



Point of Care Testing Model (POCT)

- Glucose monitoring (i.e., hemoglobin A1C)
- Cardiovascular screening (i.e., Cholesterol screening)
- Infectious diseases (i.e., Hepatitis C testing)

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Primary IVD-Pharmacy Business Models

Point of Collection

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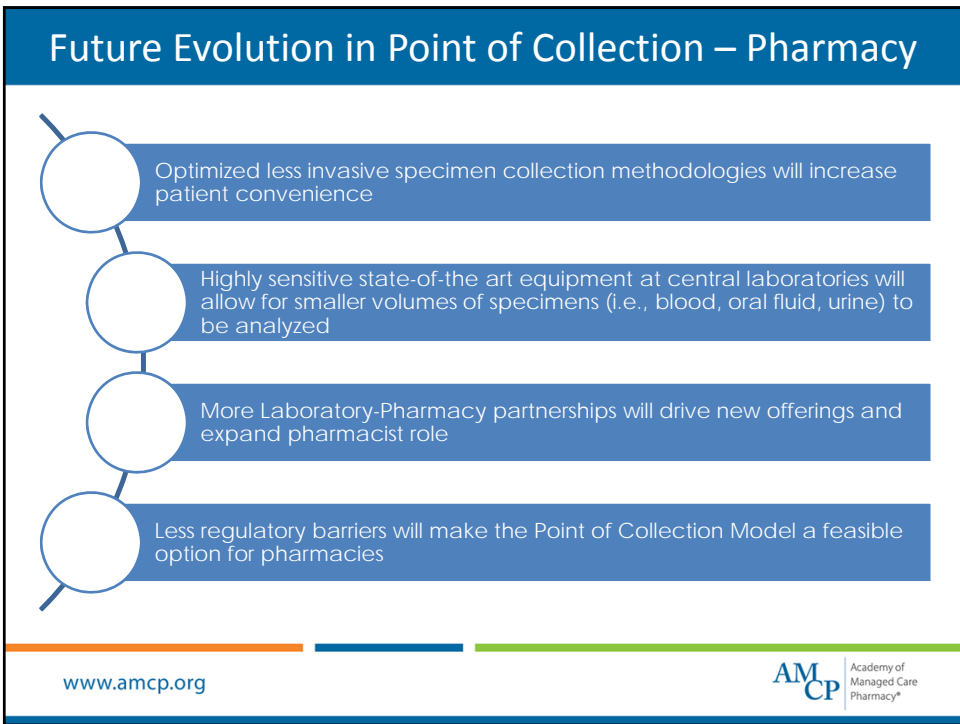
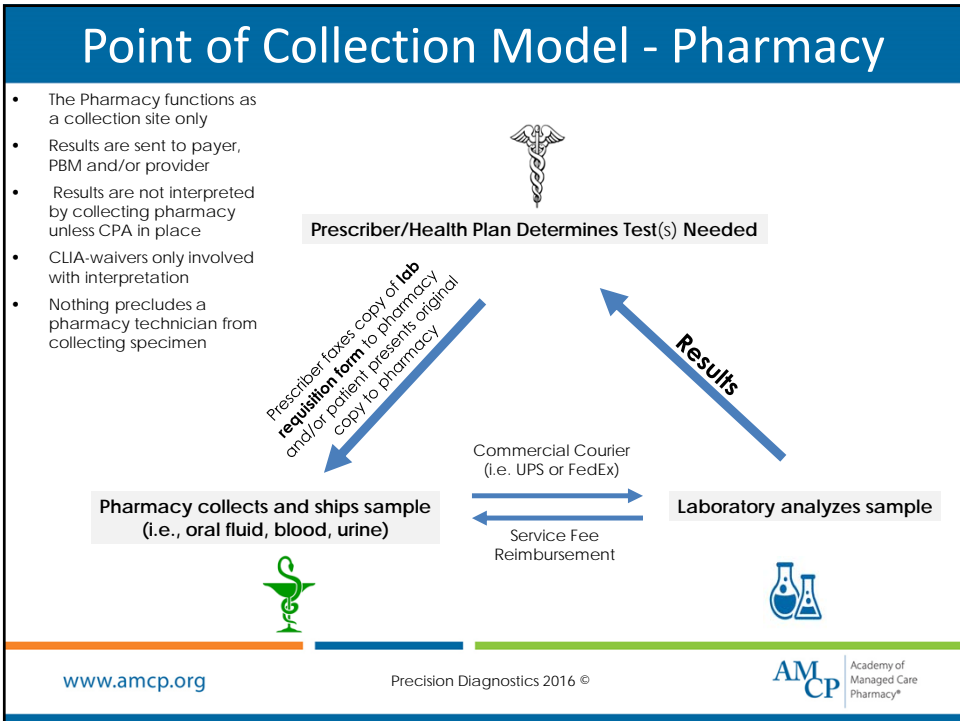
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Point of Collection Model - Pharmacy

- As more laboratory diagnostic companies begin to partner with pharmacies and pharmacists, the applications of various testing models will be considered (i.e., pharmacy collection model).
- Certain point of care technologies are not advanced enough or particularly accurate enough for certain diagnostic sectors (i.e., TDM, Pharmacogenomic testing, Addiction Treatment & Substance Abuse Monitoring, Objective Medication Adherence Monitoring).
- Health Plans and PBMs may find that the addition of the community pharmacist into laboratory diagnostic processes adds an additional eye to the ordering of lab tests and could therefore decrease the likelihood of the overutilization (i.e., ordering) of tests and costs incurred on health plans.
- The community pharmacy collection model provides the pharmacy profession with an early step into developing the laboratory-pharmacy relationship and preparation for the evolution of diagnostics into the pharmacist patient care process.
- Technological advancements in specimen collection methodologies (i.e., oral fluid) and central laboratory technology (i.e., LC/MS/MS) have enabled unique specimens be analyzed with preserved integrity.

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Primary IVD-Pharmacy Business Models

Point of Care Testing

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Point of Care Testing – Pharmacy


- Defined as a “diagnostic test performed at or near the site of patient care”
- Glycosylated hemoglobin (A1C) and cholesterol screenings have been conducted by community pharmacists since the early 2000s.
- Point of care testing devices require a CLIA-waiver, tests that the FDA has determined to have little risk on a patient if there is an erroneous result.
- Require the pharmacist to interpret results appropriately and make therapeutic and/or lifestyle recommendations

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> 120 CLIA-Waived Tests in U.S.

- Blood Glucose
- Fecal occult blood
- Pregnancy
- Cholesterol
- Triglycerides
- Thyroid Stimulating Hormones
- Hemoglobin A1C
- Influenza
- Group A Streptococcus
- HIV
- Hepatitis C
- Respiratory Syncytial Virus
- Mononucleosis
- H. Pylori

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Advantages of POCT in Pharmacy Practice


Identifies at-risk patients to refer them to next level of care for a more thorough diagnosis and treatment of an acute or chronic condition

POCT can enhance continuity of care by providing cumulative results on the progression of a disease between physician visits

Pharmacists can become involved with their own patients care by making therapeutic interventions tailored to the patient and patient test results and further elevate the pharmacist-patient relationship

POCT through pharmacies can increase access to targeted subpopulations (i.e., individuals infected with influenza)

Rodis JL, Thomas RA. Stepwise Approach to Developing Point-of-Care testing. J Am Pharm Assoc. 2006;46(5):594-604.

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General Requirements for POCT in the Pharmacy

Broad Collaborative Practice Agreement

+

CLIA-Waived Device

+

Trained Pharmacist

Enables pharmacist to interpret results and take action in collaboration with physician

FDA determines that an erroneous result from the device does not pose significant risk to the patient

- Limitations (i.e., false positives, false negatives) of the POCT devices
- Proper collection of specimen
- Correct interpretation of results
- Correct therapeutic or lifestyle intervention

Convenient Care: Point of Care Testing in the Pharmacy. NACDS. 2014. http://tse.nacds.org/presentations/2014/monday/Convenient_Care_PO_C_Testing_in_the_Pharmacy.pdf. Accessed January 20, 2016.

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Potential for POCT in the Pharmacy

- 15 million visits for acute pharyngitis each year in the US
- \$224-\$539 million in annual economic burden
- 3,000 – 49,000 people die each year from influenza.
- Most cases are not diagnosed within 48 hour treatment window

POCT Early Diagnosis Potential

- Annual treatment costs exceed \$116 billion
- 8% of the population of the United States has an undiagnosed dyslipidemia
- Estimated that 240,000 individuals in the United States are undiagnosed with HIV
- ~1 million people undiagnosed
- Leading cause of hepatocellular carcinoma and liver transplant

Convenient Care: Point of Care Testing in the Pharmacy. NACDS. 2014. http://tse.nacds.org/presentations/2014/monday/Convenient_Care_PO_C_Testing_in_the_Pharmacy.pdf. Accessed January 20, 2016.

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The Future of Point of Care Testing

5-10 years into the future of community pharmacy-based IVD

Pharmacists will have an increasing role and understanding of point of care diagnostics


Point of collection and POCT will be the norm (i.e., immunization model)

Point of Collection and POCT will be provided under MTM or disease state management programs

- 1) Improved **outcomes and quality of care**
- 2) Enhanced **patient safety**
- 3) **Increased time for physicians** to focus on critical patients
- 4) Reduce **overall costs on healthcare**

Exploring Pharmacists' Role in a Changing Healthcare Environment. Avalere Health, LLC. Published May 21, 2014. <http://www.avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>. Accessed January 22, 2016


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Examples of POCT Devices

Quidel TM Sofia Influenza A + B FIA [®]

Employs immunofluorescence to detect influenza A and influenza B viral nucleoprotein antigens




- CLIA Waived Device**
- Specimen type:** nasal swab, nasopharyngeal swab, nasopharyngeal aspirate/wash
- Time to results:** 15 minutes

Sofia Influenza A + B FIA [®] [package insert]. San Diego, CA. Quidel Corporation. 2014.

Alere TM+ Cholestech LDX [®]


Combines enzymatic methodology and solid phase technology to measure total cholesterol, HDL cholesterol triglycerides and glucose



- CLIA Waived Device**
- Specimen type:** Whole blood (finger stick or venipuncture)
- Time to results:** 5 minutes

Cholestech LDX [package insert]. San Diego, CA. Alere. 2013.

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How to Ask A Question

The screenshot displays a GoToWebinar control panel. At the top, there is a menu with 'File', 'View', and 'Help'. Below this is an 'Audio' section with options for 'Telephone' and 'Mic & Speakers' (which is selected and has a 'Settings' link). A 'MUTED' indicator is visible. The 'Questions' section is a large text area with a placeholder '[Enter a question for staff]' and a 'Send' button. An arrow points from the text 'Type your question in the 'Questions' area' to the text input field.

Type your question in the 'Questions' area