

DIRECT ACCESS TESTING: THE PROS AND CONS OF CONSUMER-DRIVEN TESTING

As a medical consumer, you can get tested for anything these days—checking cholesterol levels, determining your predisposition for cancer, finding out the paternity of your child—if you're willing to pay the price. Direct access testing (DAT) provides the opportunity for patients to take active control of their own health care, but as the DAT industry continues to grow, it is important to understand the advantages and disadvantages.

DAT GROWS FROM CONSUMER NEEDS

As consumers become more informed and information driven, they are taking measures to control their healthcare, & in turn, pushing the direct access testing industry to accommodate their needs.

WHAT IS DIRECT ACCESS TESTING (DAT)?

The Centers for Medicare & Medicaid Services defines DAT as "Consumer (as opposed to physician) initiated testing of human specimens"

DAT is commonly referred to as:

Direct-to-consumer Patient-authorized Consumer-driven Self-ordering

DAT INDUSTRY GROWTH



According to Kalorama Information, DAT lab tests created **\$33.1 million** in revenue in 2015

There is a **30%** projected annual growth over the next 5 years

35% U.S. states allow direct access testing

COMMONLY ORDERED TESTS

- 1 CBC with differential
- 2 Semen analysis
- 3 Lipid panel
- 4 HIV antibody status
- 5 Allergen-specific IgE
- 6 ABO/Rh blood typing
- 7 Hepatic function panel
- 8 Rapid plasma regain
- 9 Comprehensive metabolic panel
- 10 Thyroid-stimulating hormone
- 11 Prostate specific antigen
- 12 Therapeutic drug monitoring
- 13 Culture & antibody sensitivity

PAYMENT METHOD

- Primarily patient direct pay
- Most insurance does not offer reimbursement

FACTORS DRIVING THE DAT INDUSTRY

- Age: Aging population
- High deductibles and co-pay
- Treatment monitoring
- Internet makes research available
- Increasing number of uninsured patients
- Chronic disease monitoring
- More informed public
- Early detection of health issues

THE PROS & CONS OF DAT

Direct access testing brings specific and immediate benefits to consumers, though there are certain disadvantages to consider.

PROS OF DIRECT ACCESS TESTING

- Provides direct access to tests
- Allows patients to take an active role in their own health
- Patients and physicians can collaborate on finding appropriate tests for patients to purchase independently
- Can save money on doctor's visits
- Convenience

CONS OF DIRECT ACCESS TESTING

- Physicians may lose control over patient management
- Inability of consumers to interpret test results
- Physicians have access to patient's family history & other information affecting test interpretation
- Rising costs of tests as demand increases
- Laboratories taking advantage of consumers health concerns using fear tactics
- Tendency towards hypochondria
- False security for "normal" results or false panic for "abnormal" results

UNDERSTANDING LABORATORY REGULATIONS

The Clinical Laboratory Improvement Amendments (CLIA) are designed to assure safety, consistency and accuracy for clinical laboratories. By following these requirements, direct access testing can continue to improve test results for patients.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

- According to the FDA, the CLIA was "established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results."
- Tests are categorized by complexity as either waived, moderate complexity or high complexity

BENEFITS OF DIRECT ACCESS TESTING CONDUCTED IN CLIA-REGULATED LABS

- Three federal agencies responsible for overseeing CLIA



Food & Drug Administration (FDA)



Center for Disease Control (CDC)



Center for Medicaid Services (CMS)

- Determining test complexity helps determine applicable CLIA requirements

PROVIDES QUALITY STANDARDS FOR BASED ON TEST COMPLEXITY IN THE FOLLOWING AREAS

- 1 Facility administration
- 2 Personnel qualifications & responsibilities
- 3 Proficiency testing
- 4 Quality control
- 5 General laboratory systems
- 6 Pre-analytic, analytic & post-analytic systems
- 7 Quality assessment
- 8 Specific cytology provisions

CONCLUSION

As the direct access testing industry continues to expand & more laboratories comply with CLIA regulations, patients eager to be proactive and manage their health will have more options for safer, reliable testing.

Working with a physician is also beneficial for interpreting tests & establishing a baseline for an individual's medical history.