

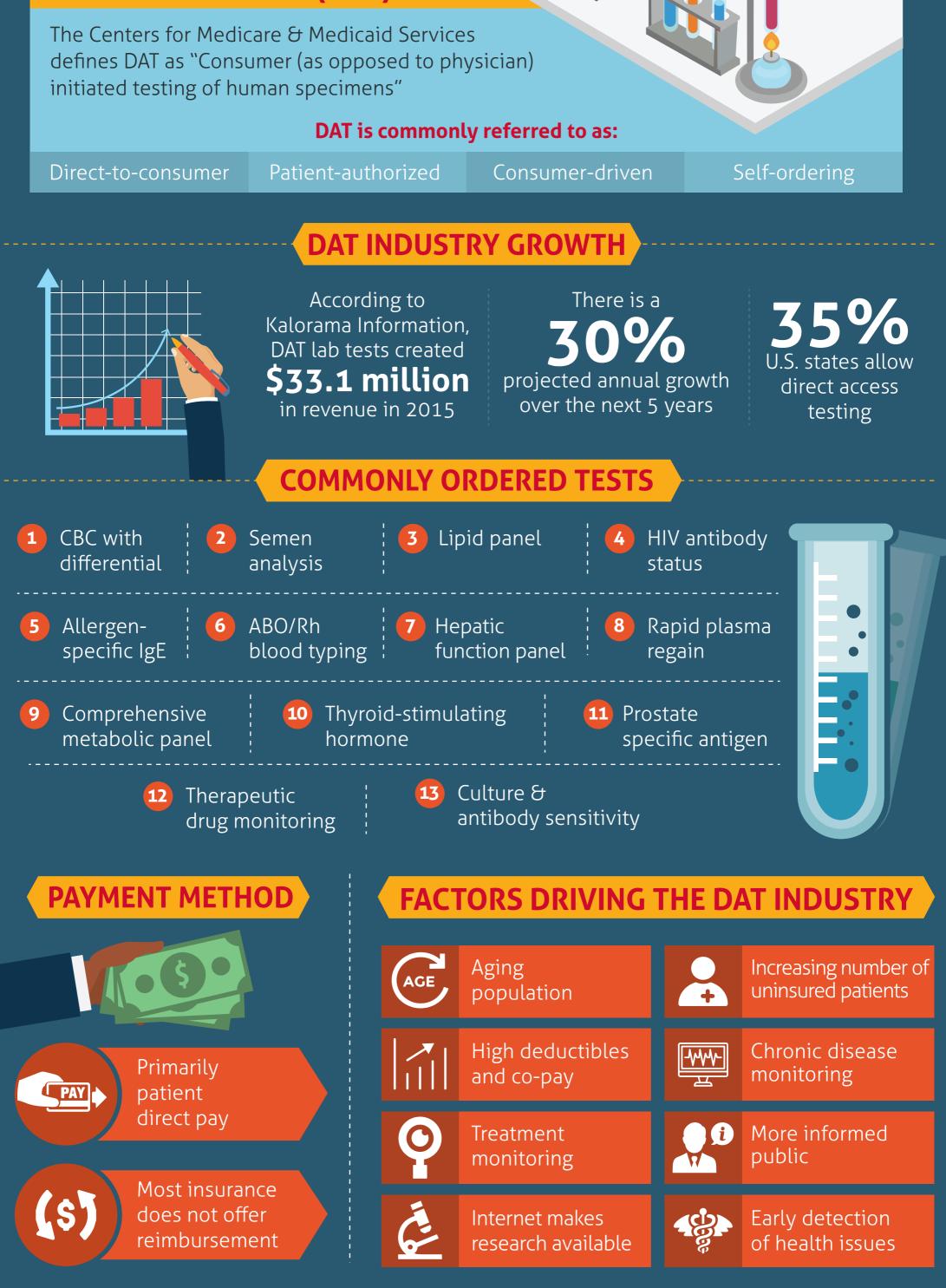
DIRECT ACCESS TESTING: THE PROS AND CONS OF CONSUMER-DRIVEN TESTING

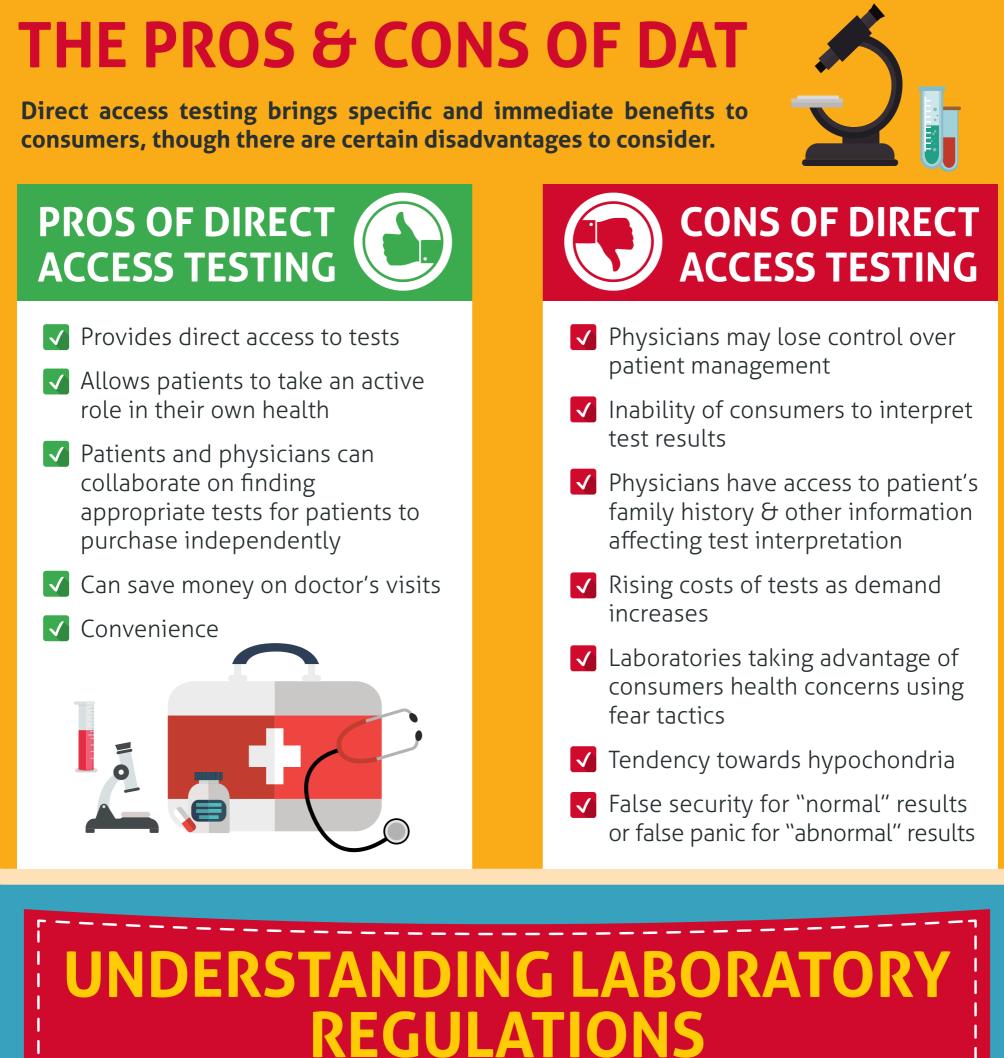
As a medical consumer, you can get tested for anything these days—checking cholesterol levels, determining your predisposition for cancer, finding out the paternity of your child—if you're willing to pay the price. Direct access testing (DAT) provides the opportunity for patients to take active control 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

informed more As become and consumers 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 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 the 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



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

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