Big Data: CMS's **Quality Improvement Evaluation System** (QIES) and **Proficiency Testing Database**

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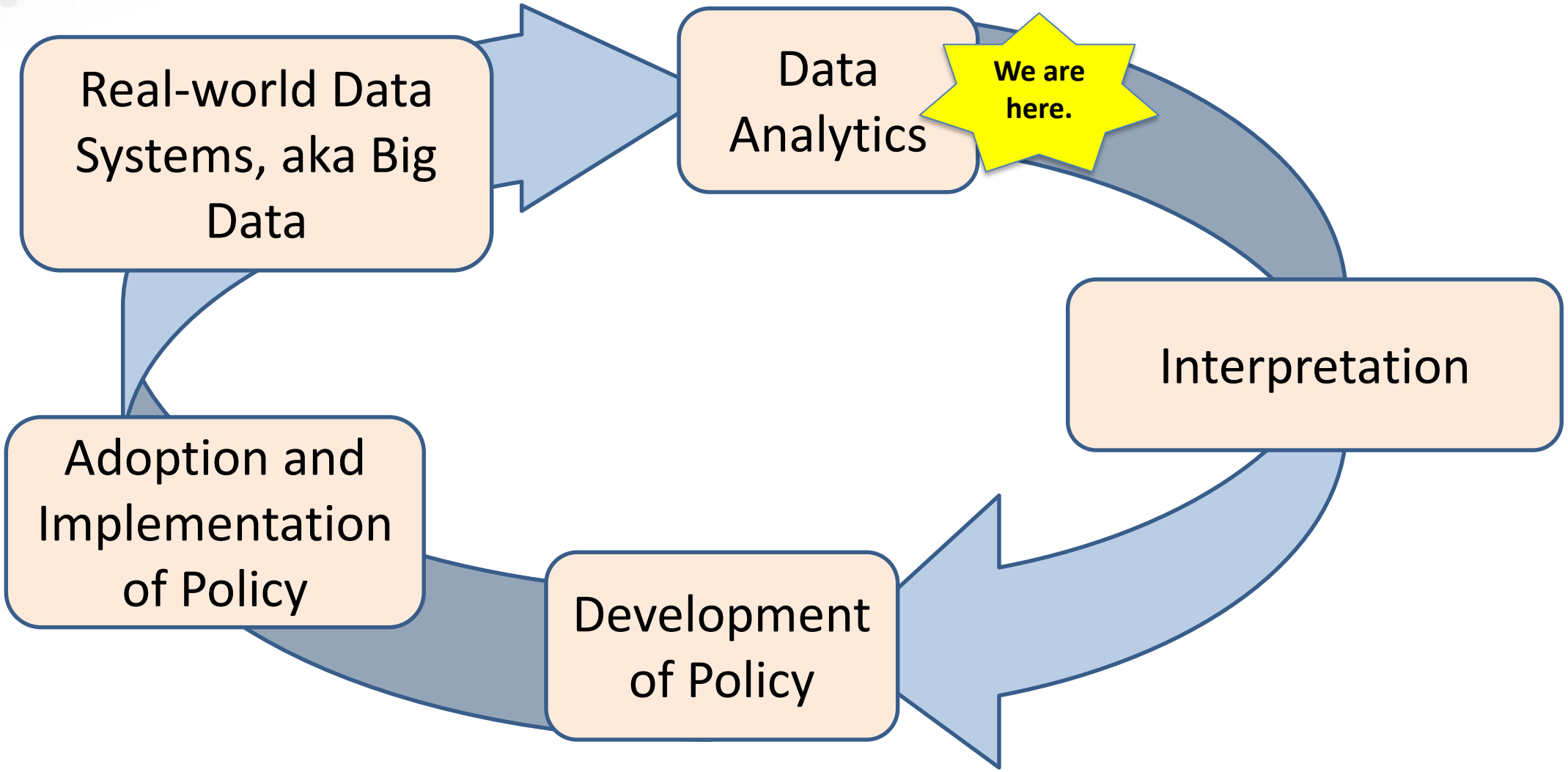
Excellent Laboratories, Outstanding Health

Scope of Talk – Data Analytics

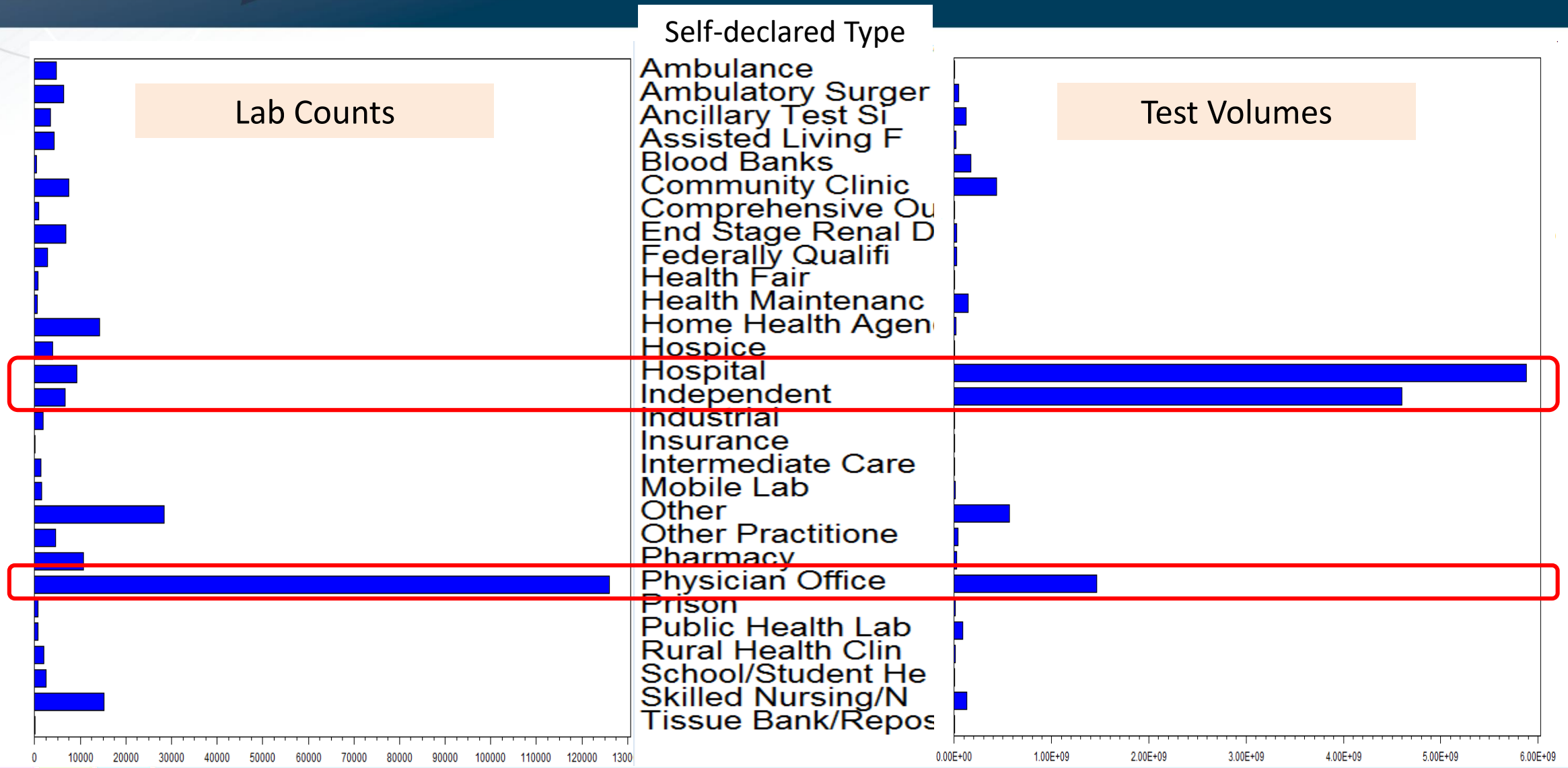
1. *Real-world Data* about CLIA Laboratories
2. CMS's QIES database *is Big Data*
   A. Certification Registration and Surveys
   B. Proficiency Testing (PT) Results
3. Challenges of using (any) Big Data
   A. Practical -IT Performance, Algorithm Development, Data Timeliness
   B. Scientific - Representative? Sample? Population? "Non-cases"
   C. "Relevance and reliability" (FDA's *Guidance* terms), aka Data Quality - Completeness, Correctness, Accuracy/Precision
   D. Regulatory – Informed Consent, HIPAA

Perspective on Data Analytics

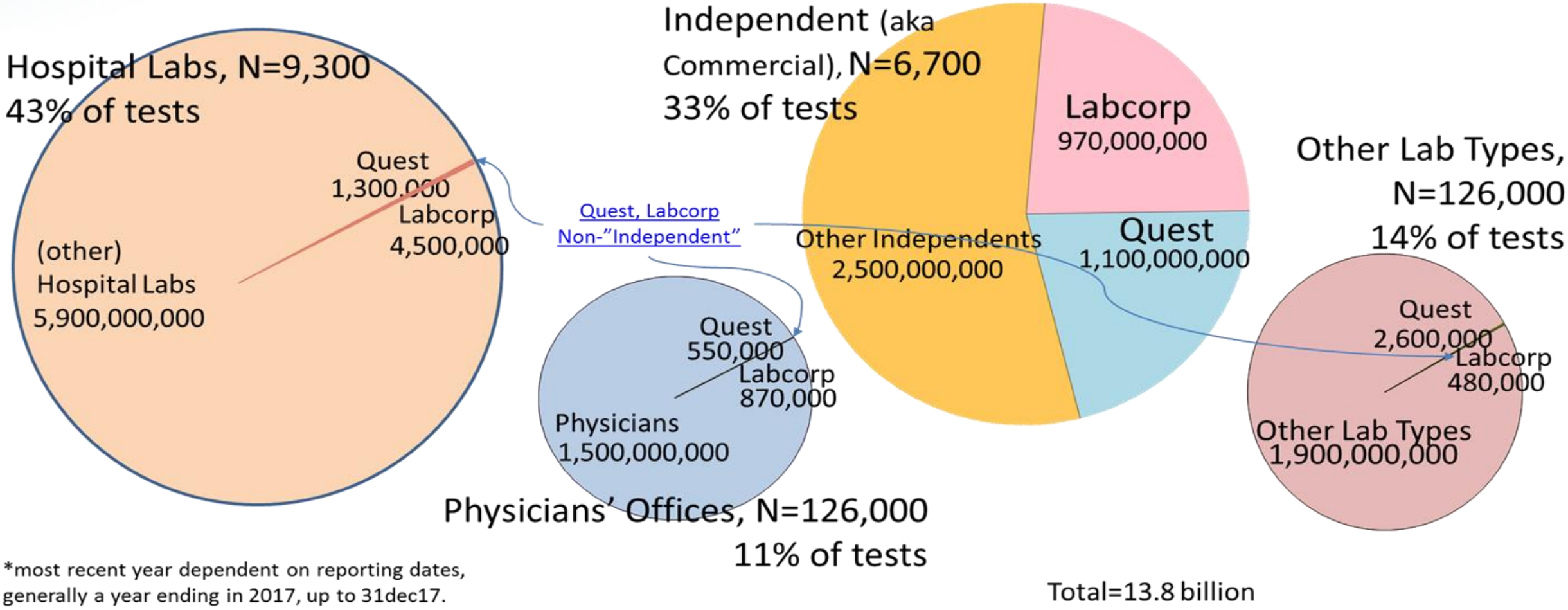


DIRECT OBSERVATIONS FROM QIES

Facility-Type: Lab Counts vs Test Volumes



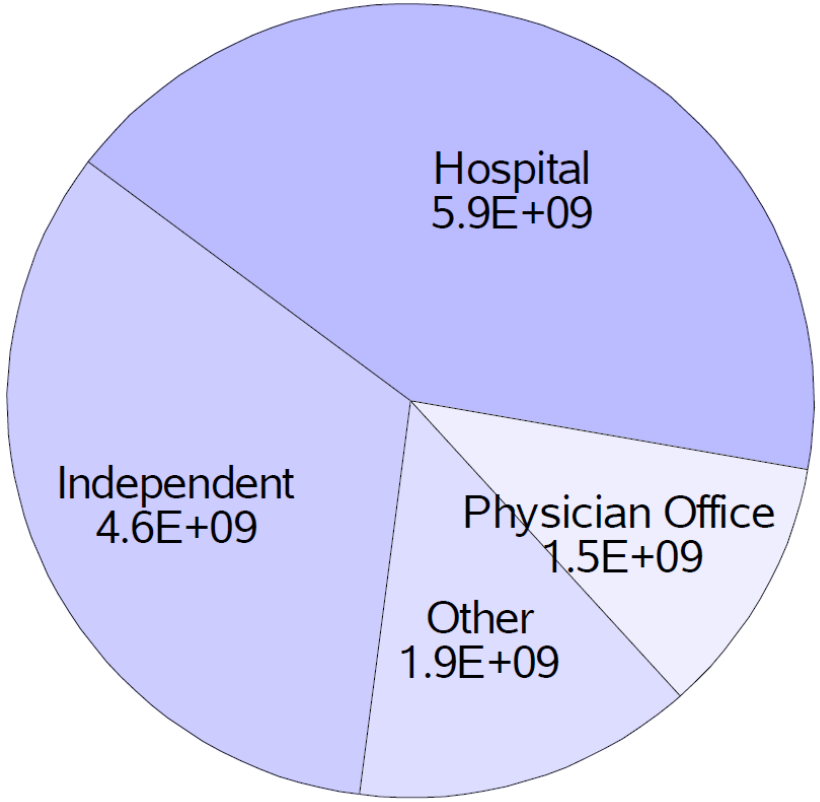
2017* Test Volume by Facility Type



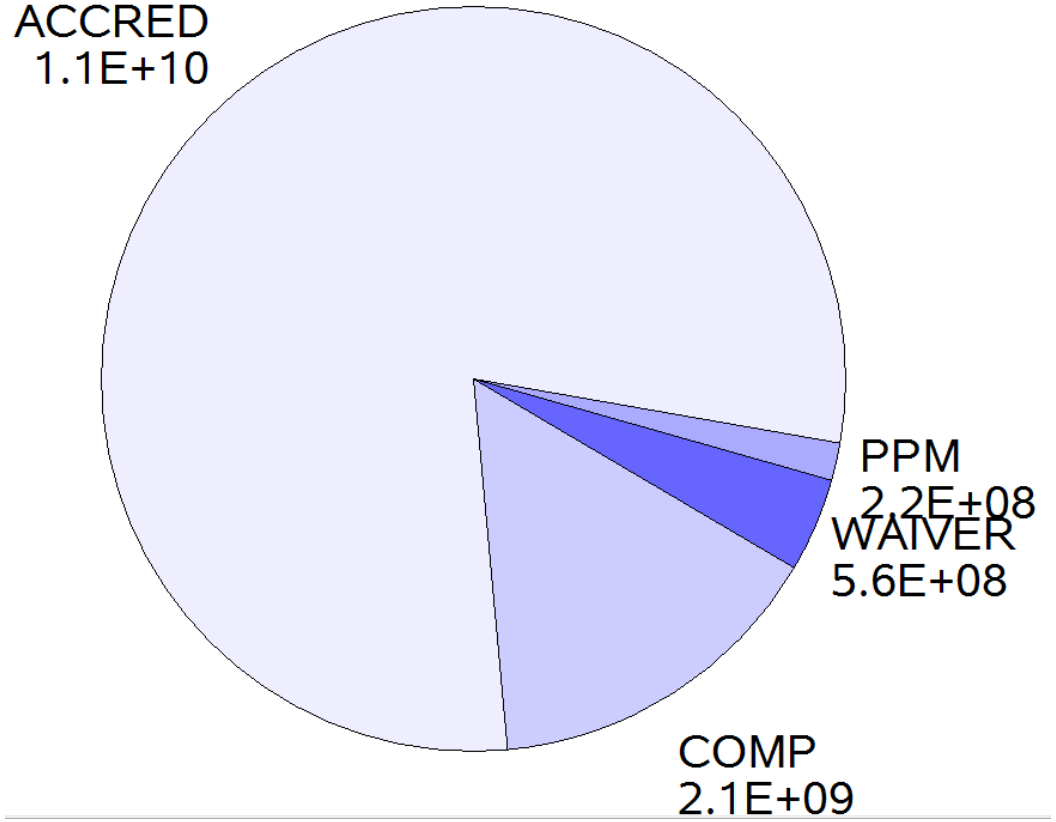
*most recent year dependent on reporting dates, generally a year ending in 2017, up to 31dec17.

Annual (2017*) Test Volume of CLIA Labs

By Facility Type EOY 2017



By CLIA Certificate Type EOY 2017



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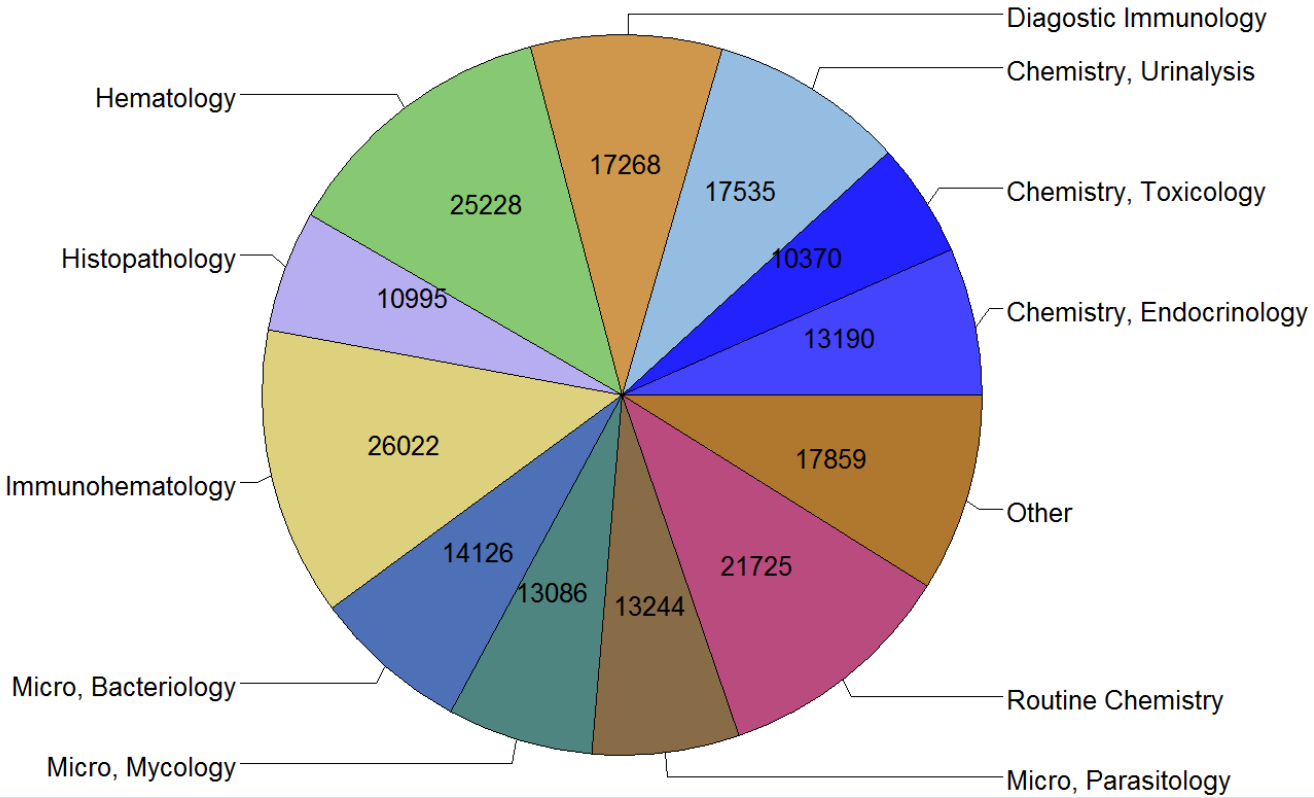
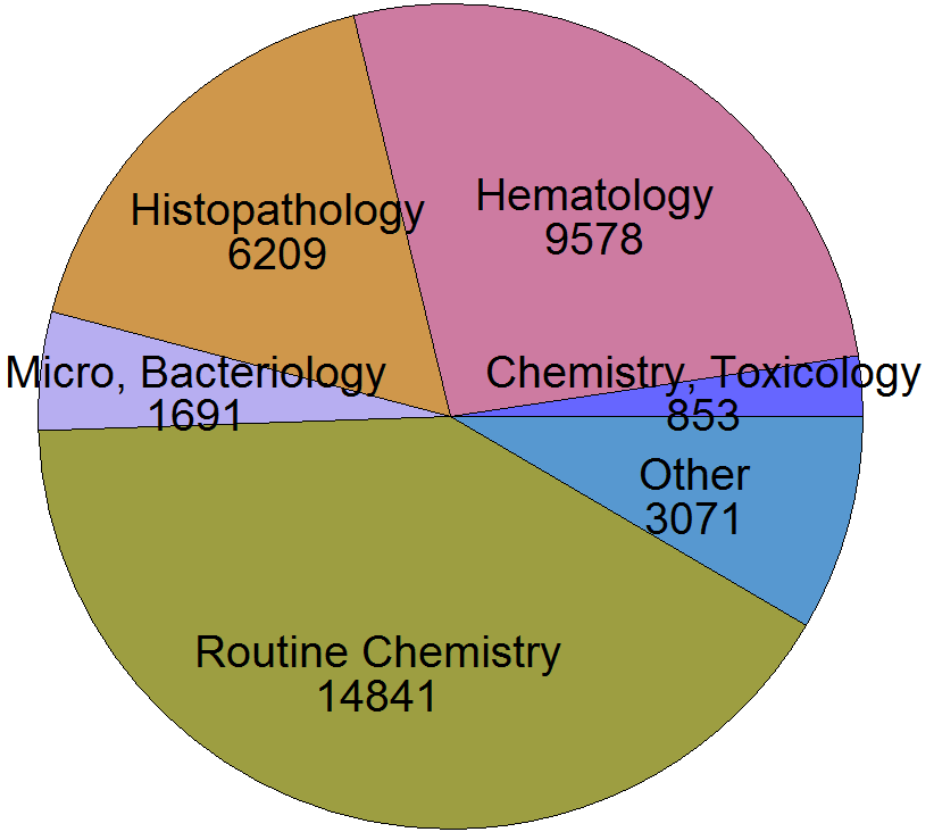
Number of Labs by Specialties

Numbers of ALL Specialties Certified, Regardless of Volume

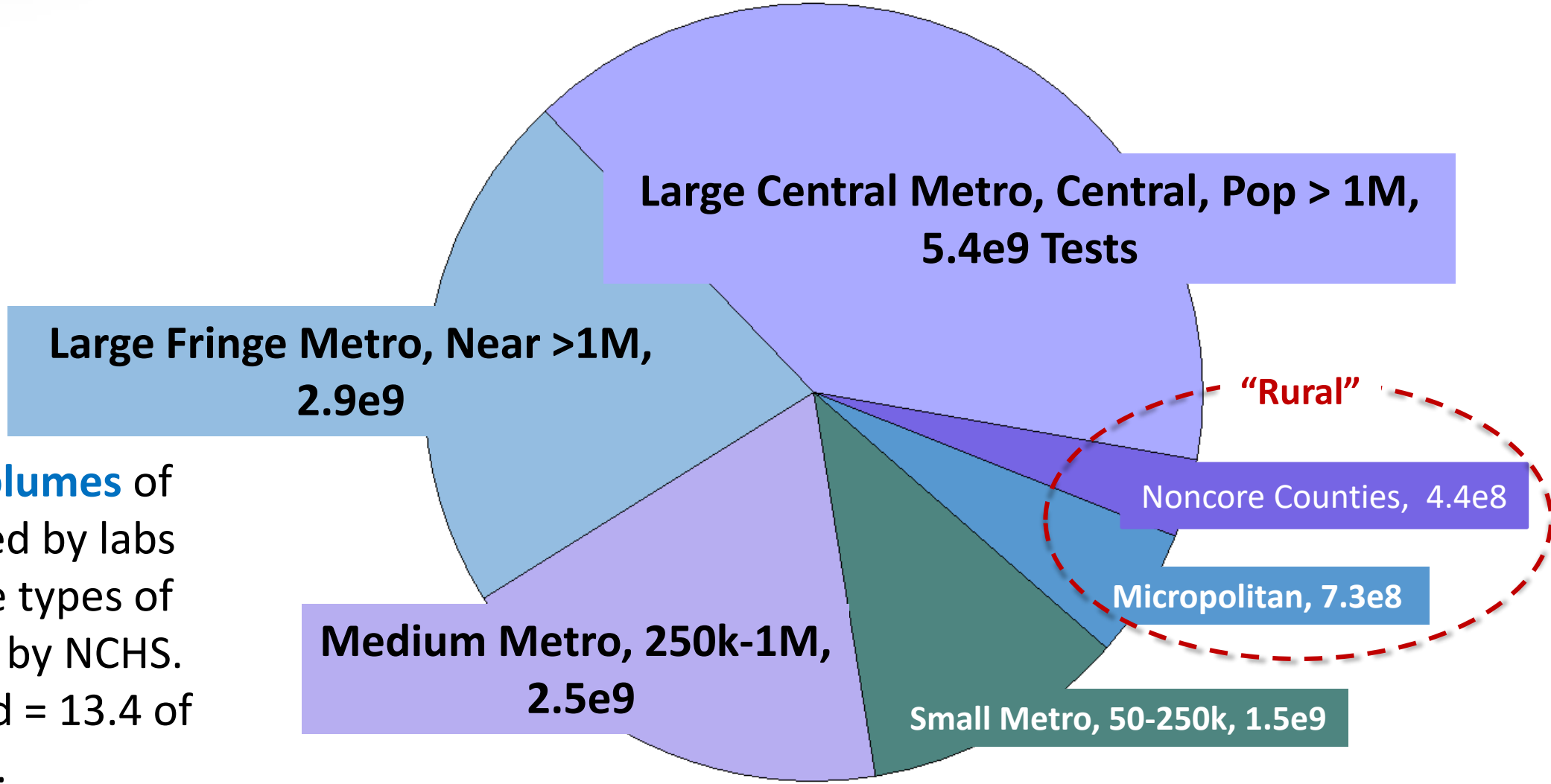


Number of Highest-volume Specialties



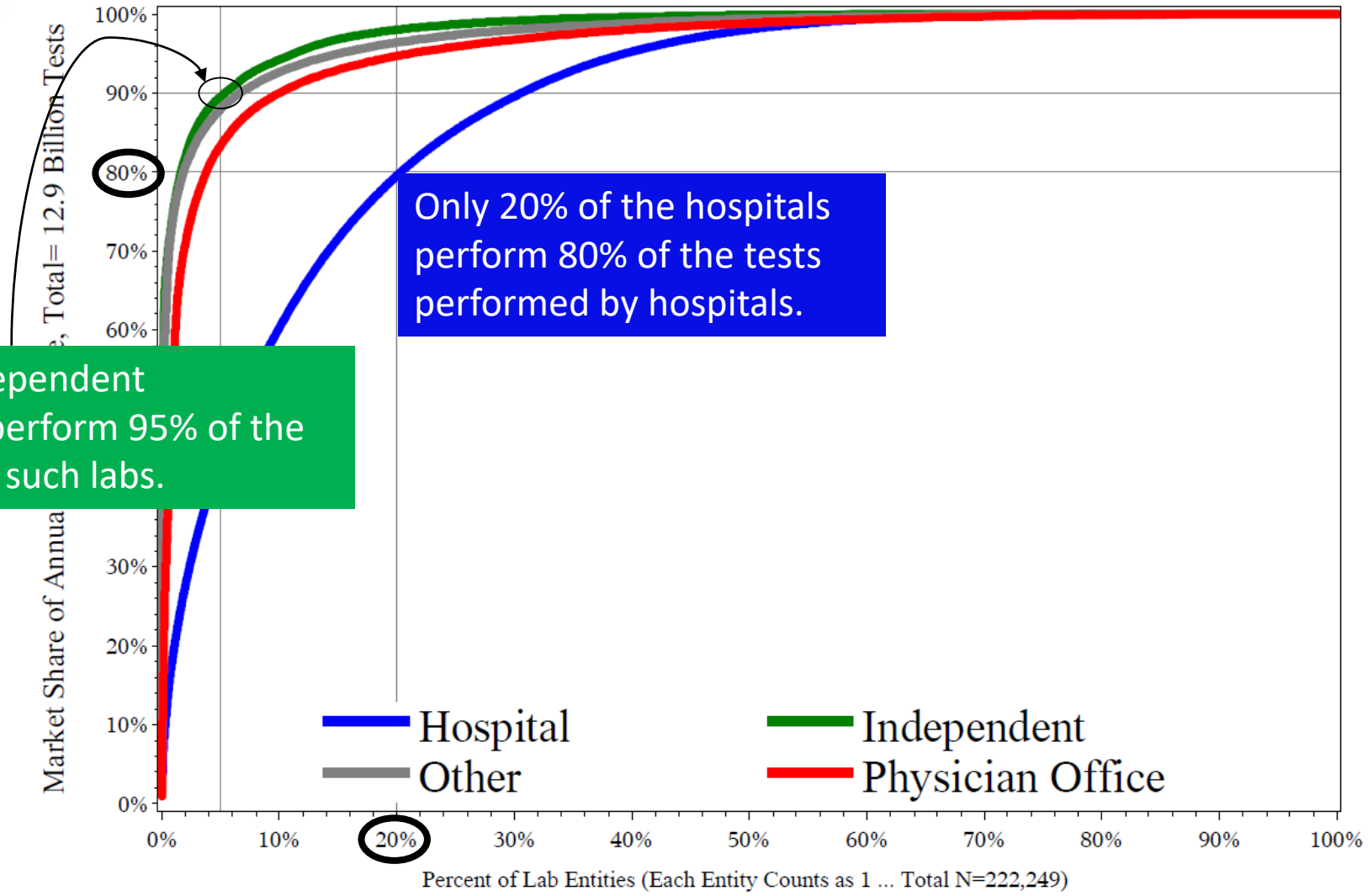
Numbers in pies are numbers of labs

Rural and Urban, National Center for Health Statistics (NCHS) Categories



These are the **volumes** of testing performed by labs certified in these types of areas as defined by NCHS. Total Categorized = 13.4 of 13.8 billion total.

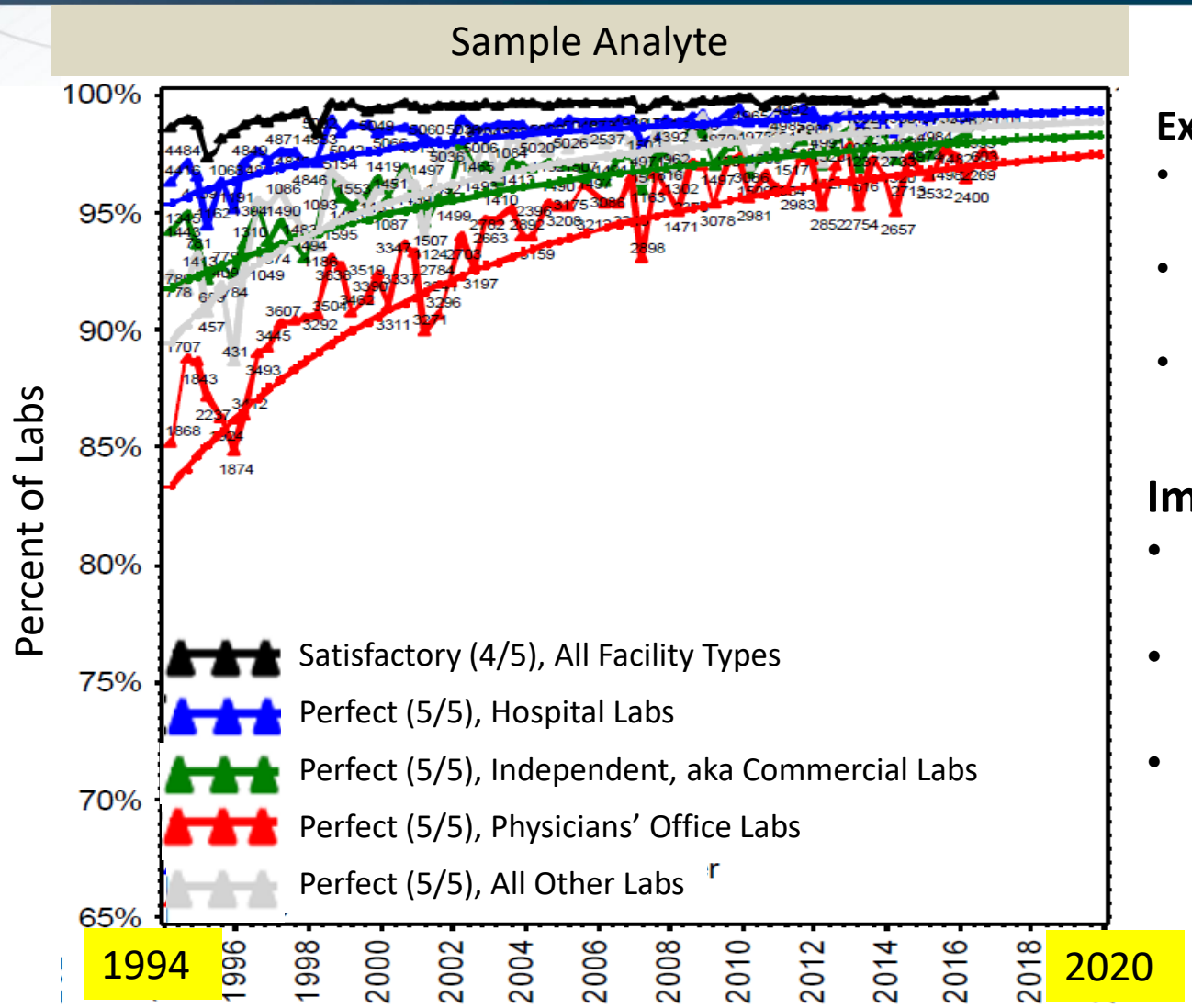
Market Distribution of Testing in U.S., 2016



Only 20% of the hospitals perform 80% of the tests performed by hospitals.

Only 5% of the independent (commercial) labs perform 95% of the tests performed by such labs.

Proficiency Testing (PT) Performance *Across Labs*



Expanded Legend

- Y-axis: Percent of Labs achieving either satisfactory (4/5=80) or perfect score (5/5=100)
- X-axis: years, 1994-2017 actual plus trend projection to 2020
- Years 2018-2020 projected *if curve-fit is appropriate*

Immediate Observations

- All facility types have improved during the CLIA period.
- Virtually all labs are satisfactory virtually all the time since about 2000 (black line).
- Hospitals have been consistently higher performing than other facility types.

NOTE: There are 86 analytes whose results are available this way.

Data Science Axioms

- A small percentage, e.g. <10%, of data that *is missing or corrupted* does not generally negate the analytical value of the remaining data.
- Fields with much greater “missingness” may still contain the best possible data set for the metric in question.
- Quality is field-by-field issue – one bad apple does not spoil the lot.

QIES Data Quality - Most of the data was present and valid most of the time. But not all.

- A total number of labs in the CLIA system, with or without various data fields in the QIES database, was 268,200 as of 12/31/17.
- The total number of labs with non-missing data for volumes and certification type was 262,600. Completeness was 98%
- The total annual test volume *for all labs reporting volume* (in any one of four possible fields) was 13.8 billion tests.
- The total test volume for labs whose reported county matched up correctly with a NCHS county name was 13.4 billion tests. 13.4/13.8=97%
- EXCEPTION: Staff figures turned out to be especially “missing”, with only 22% credible data.

Meeting Data Challenges – Cluster Analysis and Multivariable Regression Modeling, Imputation

Fact:

- 22% good data, from over 50,000 lab-samples, is still the best data we have about staff levels

Assumption:

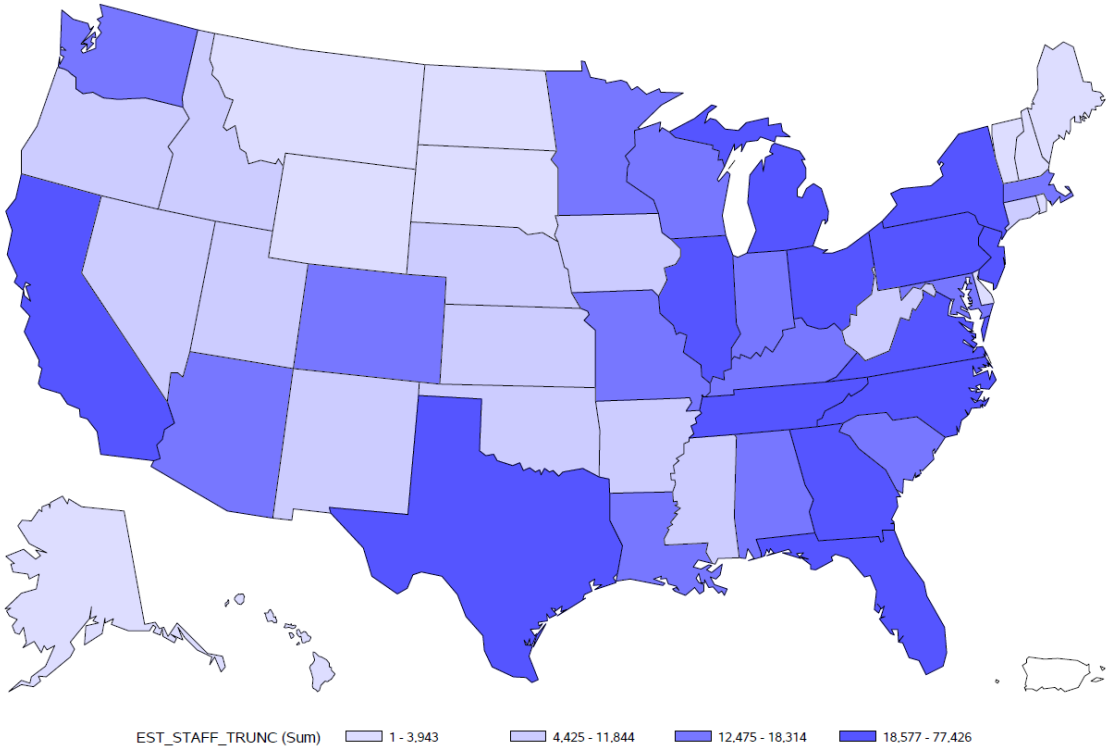
- *Tests per staff per shift* is a fundamental metric which is consistent within technologies and market segments

Approach:

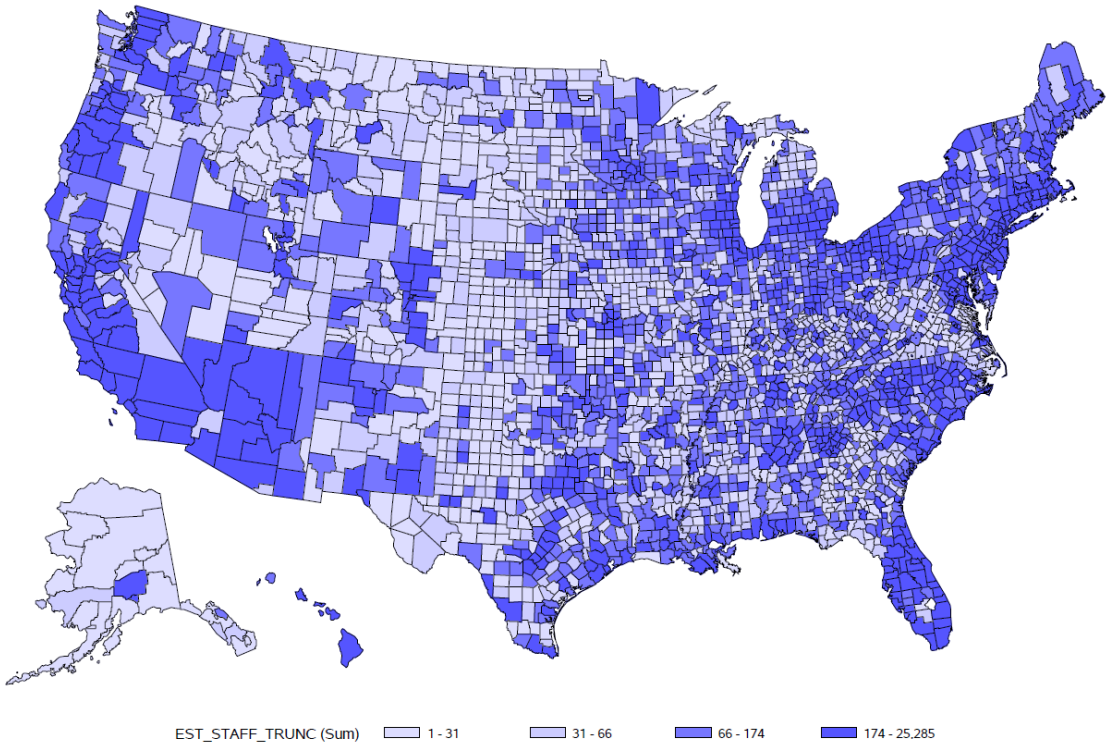
- Staff Level = *f*(technology) = *f*(proxies)
- Proxies are facility type, test volume, geography, rural/urban, specialties, et al
- QA, QA, QA!!

Workforce - Geographic Dispersion

Total Lab Staff in US States - Quartiles - ESTIMATED



Total Lab Staff in US Counties - Quartiles - ESTIMATED

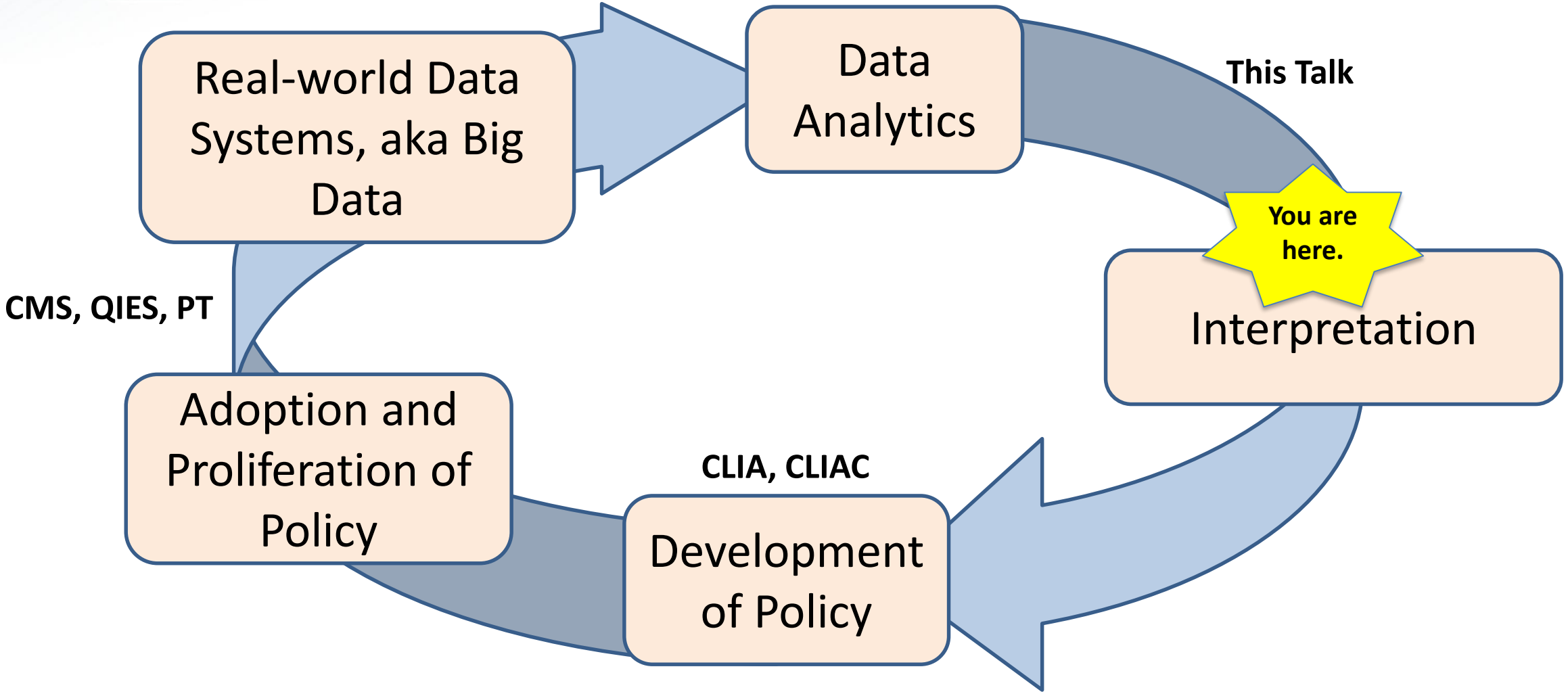


RECAP

Real-world Data

- Facility Types
- Test Volumes
- Geographic Dispersion
- Staff Levels
- Specialties
- Proficiency

Perspective on Data Analytics



Take-home Points

1. This presentation is relatively raw data; interpretation is needed.
2. The QIES database *is* Big Data.
3. Big Data presents surmountable challenges.
4. Meeting those challenges produces real-world evidence for decision making and policy development.

For more information, contact CDC
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TTY: 1-888-232-6348 https://www.cdc.gov/

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