REQUISITES FOR SUCCESSFUL PRECOMPETITIVE COLLABORATION

DIAGNOSTIC COMPANIES

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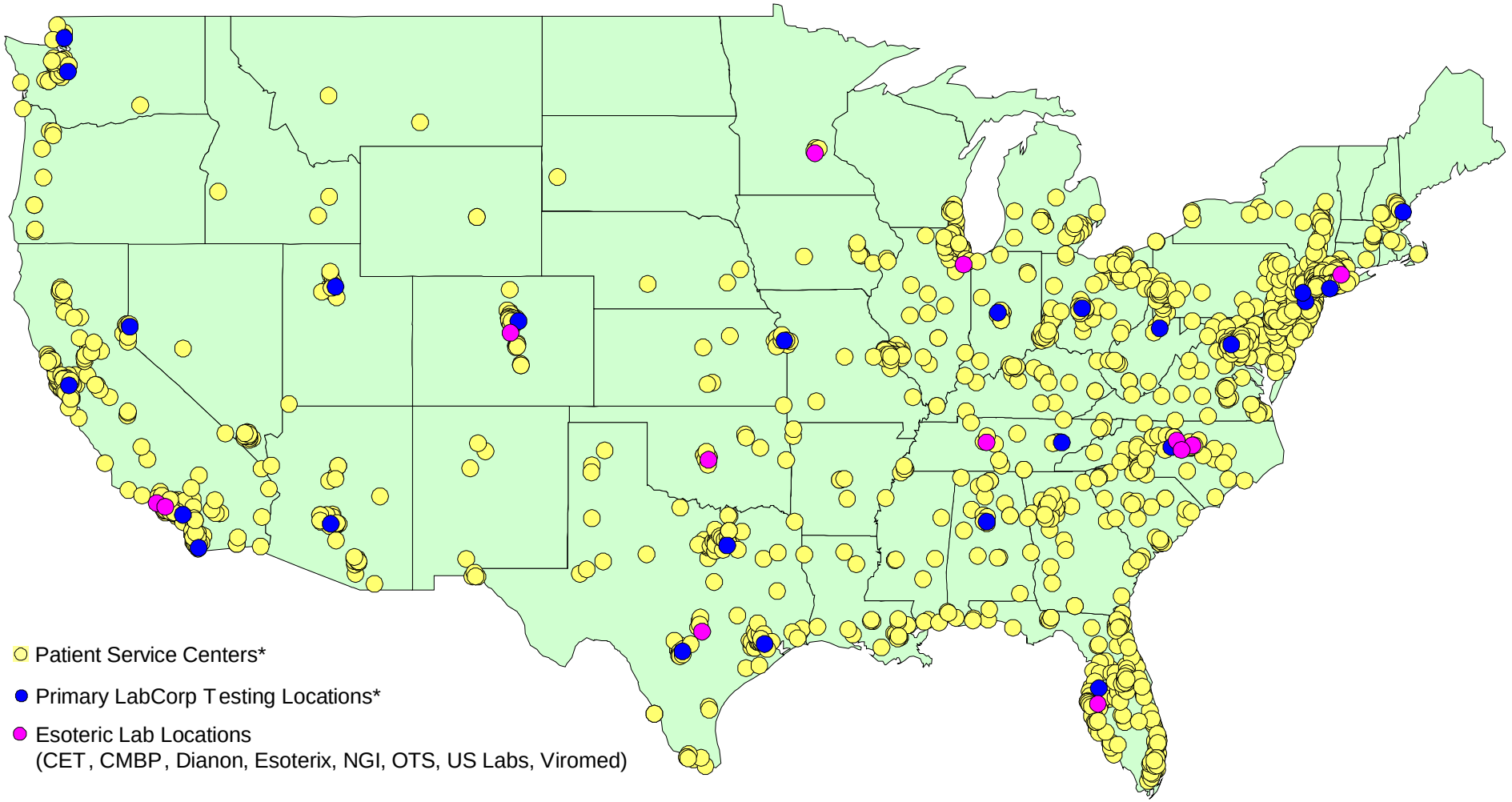
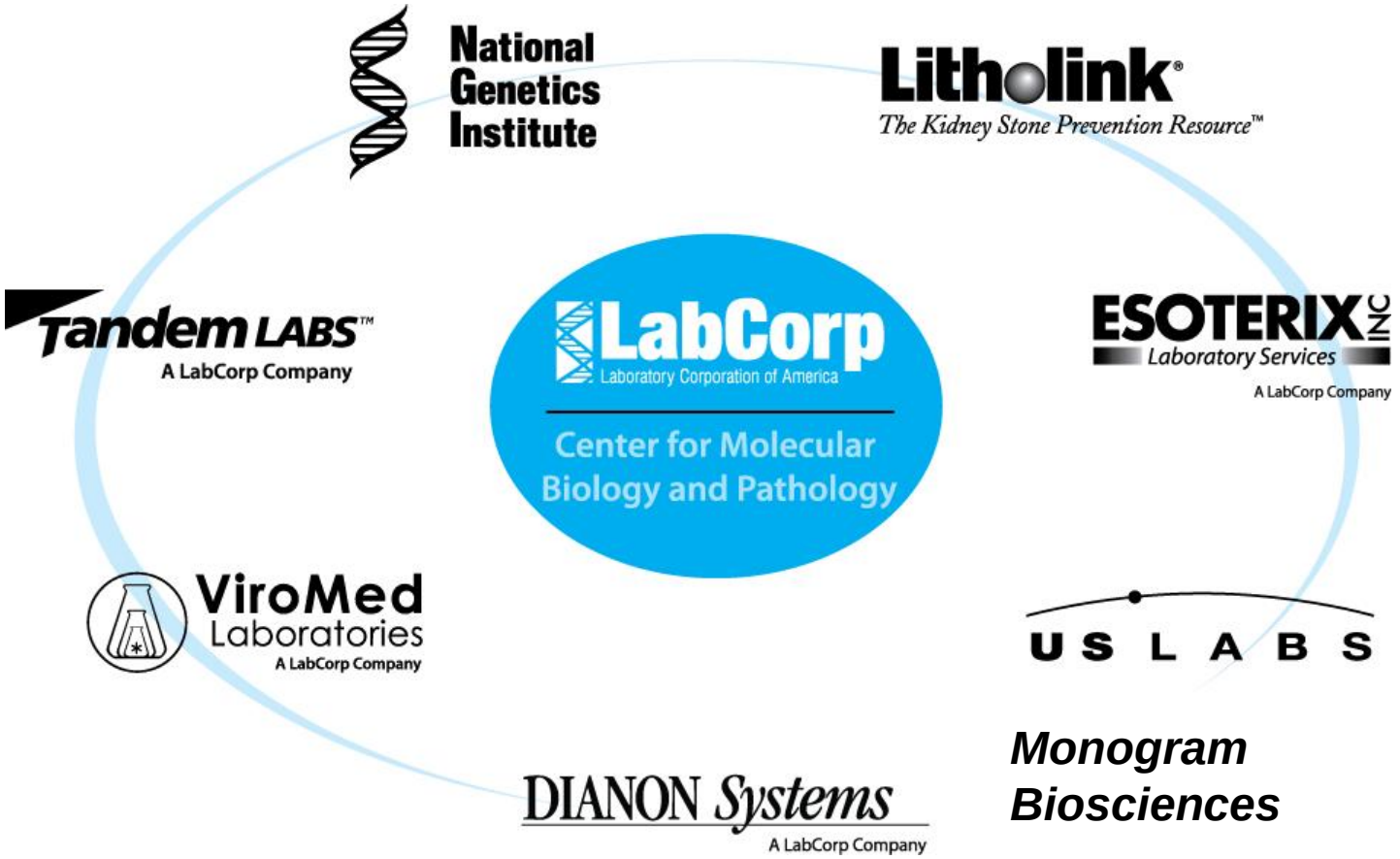
Overview of LabCorp

- More than 27,000 employees nationwide
  - 6,200 phlebotomists
  - 2,600 couriers
  - 700 MDs and PhDs
- 1,500+ conveniently located patient service centers
- $4.5B/ 4000 tests
- Highest quality, CAP inspected and CLIA certified laboratories
- National coverage
- Over 1.2 million results reported daily from 400k Specimens obtained from 220K clients
- Broadest range of clinical and anatomic pathology services to aid clinicians in diagnosis, monitoring, prediction and prevention of disease
- Connectivity with physicians offices
    - 90% of results delivered electronically
    - 70% of tests ordered electronically





To explore relevant issues related to developing a cultural, legal, and behavioral framework of collaboration that enables biospecimen and data sharing

- What does precompetitive mean?
- What are the requisites for a diagnostic laboratory?
- What is considered precompetitive?

Lab Based Questions

Positive and negative controls
Clinical residual samples – isolated DNA, RNA, metabolites from known disease/conditions
Internal quality systems and SOPs
Interpretation and reporting elements and formats
Order and requisition formatting, standards
Standards for adverse event and/or corrective action
Format and procedures for notifications
Reporting and handling of incidental findings
Variations of unknown (or emerging) significance
Polymorphisms – both disease causing and benign
Transparency on assays – i.e. panethnic panel for CF, or cancer assays for how many mutations
Nomenclature standardization – commercial marketing speech
Registration of tests – instrumentation, reagents, assays, protocols
Practices – best and less than best
Data transparency, levels of evidence
Grey literature support
Health information exchange systems within the labs and within the systems connected to the labs

Current Bar

Science based, regulatory, guidance statements (guidelines)

Positive and negative controls –purchased or in FDA approved kits

Reporting elements

Nomenclature standardization –mutation designation

Clinical residual samples – isolated DNA, RNA, metabolites from known disease/conditions – annonymized samples

Polymorphisms – both disease causing and benign

Grey literature support

Health information exchange systems within the labs and within the systems connected to the labs – already standardized EMR languages

Easily achievable Bar

Regulatory, required

Internal quality systems
Standards for adverse event and/or corrective action
Reporting and handling of incidental findings
Practices – best and less than best
Format and procedures for notifications

Interpretation (non FDA approved kits)
Nomenclature standardization – commercial marketing speech

Variations of unknown (or emerging) significance

Registration of tests – instrumentation, reagents, assays, protocols

Data transparency, levels of evidence
Grey literature support

Difficult Bar to meet

Some push due to regulation

SOPs
Interpretation formats
Order and requisition formatting, standards

Format and procedures for notifications
Practices – best and less than best

Transparency on assays – i.e. panethnic panel for CF, or cancer assays for how many mutations

Registration of tests – instrumentation, reagents, assays, protocols- will likely be required

What will keep the bar from moving

- technologies/tests/acquired IP licensed directly to laboratories (exclusive, or non-exclusive)
- Compliance issues – legal concerns

What will push the bar

- FDAs regulatory strategy for laboratory-developed tests and
- The involvement of CMS and CLIA certification