COLLEGE of AMERICAN PATHOLOGISTS

CAP's Recommendations to the Office of Management and Budget

Meaningful Use of Certified Electronic Health Record Technology

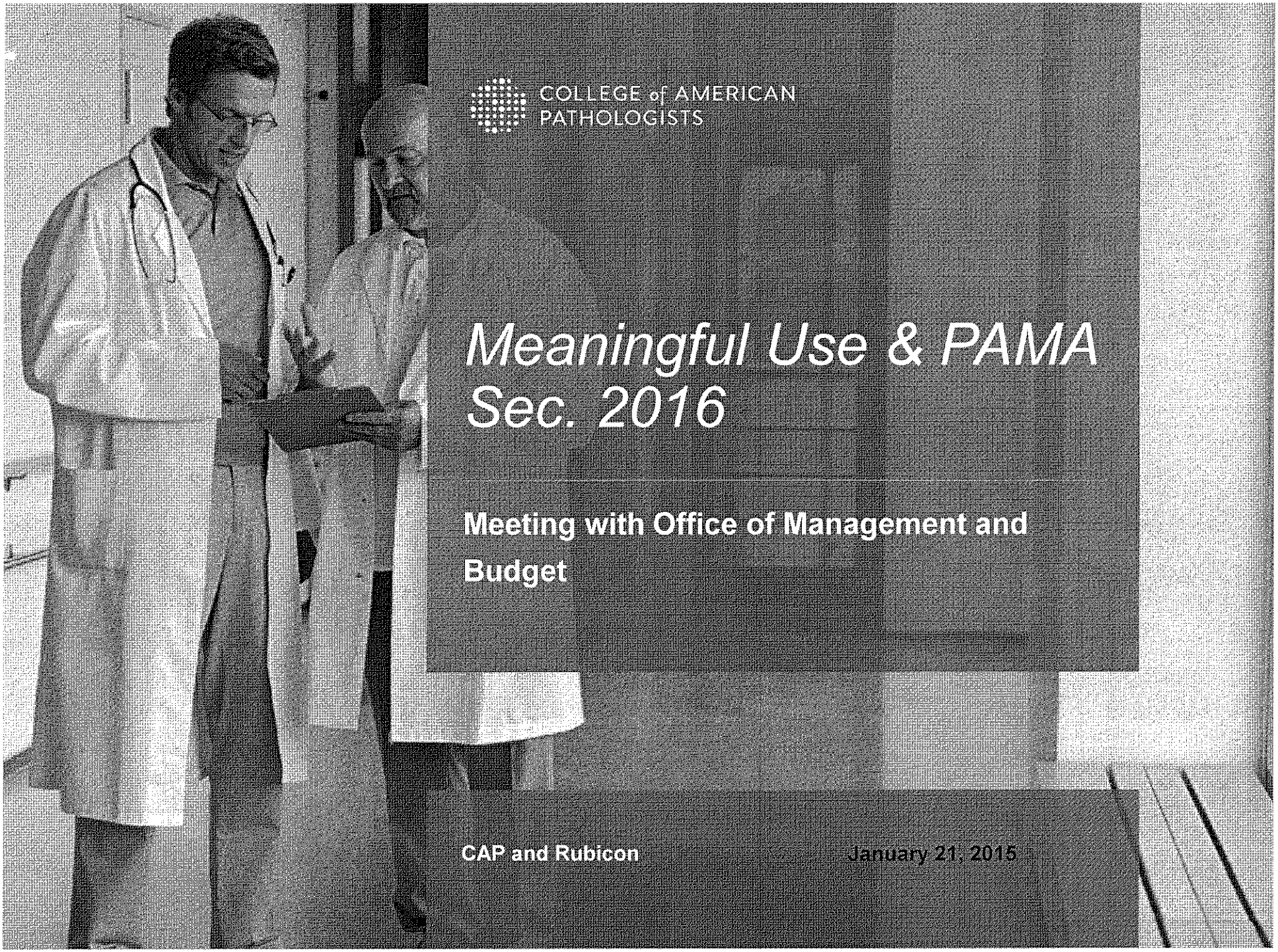
- *The Stage 3 rule for Meaningful Use should continue the Significant Hardship Exception (SHE) for pathologists for 2016.*

PAMA Reporting of Payments for Laboratory Tests

- *New payment rates for the CLFS should reflect, to the greatest extent possible, the full range of laboratories performing the test. CMS should limit exceptions to the reporting requirements.*
- *CMS should require hospital laboratories (TINs) that provide the majority of their CLFS services for non-patients to participate in reporting.*
- *CMS should identify a low-volume or low-expenditure threshold that will minimize the reporting burden for very small laboratories. Any potential threshold should not significantly change the weighted median payment rate.*

Coding and Coverage of Advanced Diagnostic Laboratory Tests

- *CMS should use four Medicare Administrative Contractors (MACs) to administer coverage and claims payment for the Clinical Laboratory Fee Schedule.*
- *If one MAC is making local coverage decisions that will be implemented nationwide, CMS should use the National Coverage Decision (NCD) process, NOT the Local Coverage Decision (LCD) process.*
- *CMS should use HCPCS Level I (CPT) codes whenever possible. CPT codes should be used as the "unique identifiers" for tests; CMS should maintain current multi-stakeholder process for assigning CPT codes; and use only HIPAA-compliant code sets.*
- *"Advanced diagnostic laboratory tests" should be defined as single source laboratory tests that:*
  - *Analyze multiple biomarkers using unique algorithmic analysis, OR*
  - *Are cleared or approved by FDA, OR*
  - *Cannot be included in an existing HCPCS Level I (CPT) code.*
- *New tests that can be assigned to an existing molecular pathology Tier 1 or Tier 2 CPT code should be categorized as such, and paid at the National Limitation Amount (NLA). Laboratory tests that have a new CPT code should receive open consideration of Medicare coverage, just like other medical services that receive a new CPT code.*
- *Tests that do not fit into an existing CPT code are "advanced diagnostic laboratory tests" and should receive a temporary HCPCS Level II code. At the conclusion of the two-year period of Medicare coverage specified in statute, CMS should issue a formal sunset list for tests whose temporary HCPCS Level II code is expiring.*
- *CMS should also end the practice seen in the MolDx program of using coding to distinguish between FDA-cleared or approved tests and laboratory developed tests (LDTs.)*


COLLEGE of AMERICAN
PATHOLOGISTS
Meaningful Use & PAMA
Sec. 2016
Meeting with Office of Management and
Budget
CAP and Rubicon
January 21, 2015

Agenda

- **Introduction to the CAP**
- **Medicare and Medicare EHR Incentive Program (aka Meaningful Use)**
- **Sec. 216 "Improving Medicare Policies for Clinical Diagnostic Laboratory Tests" of P.L. 113-93 "Protecting Access to Medicare Act of 2014**
- **Preview: FDA Guidance on Laboratory Developed Tests**

CAP

About the CAP

- Established in 1946; leading organization for board-certified pathologists
- Second largest medical society in the United States
- More than 18,100 members and 600 employees
- CMS-deemed accreditor under CLIA

Pictured left: CAP Headquarters in Northfield, Illinois, a suburb of Chicago

Meaningful Use of Certified EHR Technology

- **The Stage 3 rule for Meaningful Use should continue the Significant Hardship Exception (SHE) for pathologists for 2016.**

- **Stage 2 final rule *automatically* qualified pathologists (PECOS code 22) for the Significant Hardship Exception (SHE) for 2015.**
  - **Relief based on pathologists' lack of control over the availability of Certified EHR technology at their practice locality**
  - **Nothing has changed since 2012 Stage 2 rulemaking.**

- **Only 38 pathologists have met MU in all three years (2011, 2012 and 2013)**

- **More information in the Appendix**

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PAMA "Ask"

- **Alert OMB in advance of anticipated rulemaking to CAP concerns on new law re:**
  - **Reporting requirements**
  - **Local coverage decisions**
  - **Codes for laboratory tests**

PAMA Timeline: 2014- 2015

2014

- 4/1: Enacted into law
- New payment methodologies apply to any revised HCPCS code issued after 4/1

2015

- 1/1: Medicare Administrative Contractors (MACs) required to abide by existing Local Coverage Determination Process (LCD) when issuing coverage decisions

2015 (cont)

- HHS Sec. can designate 1-4 MACs to establish clinical coverage policies & process claims for clinical diagnostic laboratory tests
- 6/30: HHS Secretary must issue rule on parameters for data collection
- 7/1: Secretary required to consult with expert advisory panel on clinical diagnostic laboratory tests

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PAMA Timeline: 2016-2017

2016

- 1/1: "Applicable" laboratories must report to CMS private market data on payment rates
- CMS must assign unique HCPCS codes & publicly report payment rates for existing tests paid by Medicare that lack codes

2017

- 1/1: Prices for clinical laboratory tests begin to be based on "weighted median" prices of private market data
- Q1-Q3: Advanced diagnostic laboratory tests (ADLTs) paid at actual charge data
- 6/30: Labs must report data on ADLTs
- Reductions to laboratory payments capped

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CAP's Goal for PAMA Sec. 216 Implementation

- **Minimize disruption to the provision of laboratory tests**
  - **Ensures widespread patient access to testing**
  - **Minimizes reporting burdens to the greatest extent allowable under the statute**

- **New law creates exceptions to reporting requirement**
  - **CMS should implement carefully**

- **Additional recommendations in Appendix:**
  - **Alternate reporting mechanisms to minimize burden**
  - **Definitions of payment terms**
  - **Civil monetary penalties**
  - **Advisory Panel**

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PAMA Reporting Requirements

- **New payment rates for the CLFS should reflect, to the greatest extent possible, the full range of laboratories performing the test.**
  - **CMS should limit exceptions to the reporting requirements.**
- **CMS should require hospital laboratories (TINs) that provide the majority of their CLFS services for non-patients to participate in reporting.**
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Coverage of Advanced Diagnostic Tests

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Codes for Advanced Diagnostic Laboratory Tests

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  - **Analyze multiple biomarkers using unique algorithmic analysis, OR**
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  - **Cannot be included in an existing HCPCS Level I (CPT) code.**

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Assignment to New vs. Existing CPT Codes

- **New tests that can be assigned to an existing CPT code should be categorized as such, and paid at the National Limitation Amount (NLA).**

- **Laboratory tests that have a new CPT code should receive open consideration of Medicare coverage, just like other medical services that receive a new CPT code.**

- **Tests that do not fit into an existing CPT code are "advanced diagnostic laboratory tests" and should receive a temporary HCPCS Level II code.**

- **At the conclusion of the two-year period of Medicare coverage specified in statute, CMS should issue a formal sunset list for tests whose temporary HCPCS Level II code is expiring.**

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Concerns About FDA Guidance on LDTs

- **CMS should also end the practice seen in the MolDx program of using coding to distinguish between FDA-cleared or approved tests and laboratory developed tests (LDTs.)**

- **CAP will seek significant changes to the FDA draft guidance; will detail in formal comments to the FDA due in February.**

- **Final FDA guidance should be consistent with CAP's principles for regulating laboratory-developed tests.**

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CAP Risk Classifications

	Principles
Low Risk	•*Test result is typically used in conjunction with other clinical findings to establish or confirm diagnosis.* •*No claim about test result alone determines prognosis or direction of therapy.* •*The consequence of an incorrect result or incorrect interpretation is unlikely to lead to serious morbidity/mortality.*
Moderate Risk	•*Laboratory may make claims about test results that inform prognosis or direct of therapy.* •*The consequence of an incorrect result or incorrect interpretation may lead to serious morbidity/mortality AND the test methodology is well understood and independently verifiable.*
High Risk	•*Test result predicts risk, progression of, or patient eligibility for a specific therapy; AND Test uses proprietary algorithms or computations such that the test result cannot be tied to the methods used, or inter-laboratory comparisons can not be performed.* •*The consequence of an incorrect result or incorrect interpretation could lead to serious morbidity/mortality AND the test methodology is not well understood or is not independently verifiable.*

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Thank You!

For more information, please contact:

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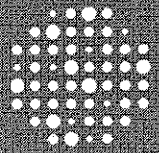

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Appendix

CMS Current Policy on MU for Pathologists

- **Stage 2 final rule *automatically* qualified pathologists (PECOS code 22) for the Significant Hardship Exception (SHE) for 2015.**
  - **CAP supported this decision**

- **Stage 2 final rule said qualification for the SHE subject to annual renewal**

- **Relief based on qualification under category for eligible providers (EPs) who**
  1. **Lack of face-to-face or telemedicine interaction with patients;**
  2. **Lack of follow-up with patients; and**
  3. **Lack of control over the availability of Certified EHR technology at their practice locality.**

    - ***Nothing has changed since 2012 Stage 2 rulemaking.***

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Meaningful Use: CAP Primary Ask

Include continuation of Significant Hardship Exception (SHE) for pathology in Stage 3 EHR/MU rule.

Relief from payment adjustments enjoys Congressional support:

- **Bipartisan, bicameral H.R. 4015, the *SGR Repeal and Medicare Provider Payment Modernization Act of 2014*, would have given HHS Secretary authority to create measures for pathologists and other physicians that do not have direct interaction with patients**

- **Reps. Tom Price (R-GA) and Ron Kind (D-WI) H.R. 4066 – the *Health Information Technology Reform Act* would exempt pathologists from MU eligibility**

- **Bipartisan Congressional interest in support of continuing SHE for pathologists**

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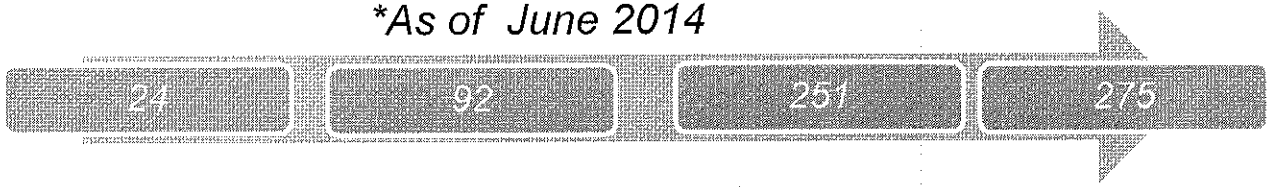
Pathologists' Participation in MU

June 2014 data downloaded from healthdata.gov

- **366 *unique* pathologists have attested in one of the four program years**
- **1045 *total* attestations by the 366 pathologists**
  - **128 pathologists attested in only 1 year**
  - **200 attested in 2 years**
  - **Only 38 attested in 3 years (2011, 2012 and 2013)**

Pathologists MU Attestations by Year

**As of June 2014*



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Challenges for Pathologists with MU (1)

- **Many objectives written from perspective of ORDERING provider**
  - **Not provider RECEIVING the order**
- **NONE of pathology PQRS measures are included in CQMs**
  - **CQMs: Measures are not e-specified**
  - **Can't report zero denominators because of lack of use of CEHRT**
- **CEHRT not appropriate clinical system for pathologists**
- **Laboratory Information Systems (LISs) designed for laboratory medicine**
  - **Link to laboratory machines**
  - **Can track non-patients**
  - **Can report to HIEs and CEHRT but communication isn't generally two-way**
- **Pathologists scope of practice different that office-based providers**
  - **Patients do not usually "present" for AP services**

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Challenges for Pathologists with MU (2)

- **Small number of pathologists meeting MU are generally at large academic integrated setting by relying on the data entries of others.**
  - **Minority of pathology practice**
  - **Vast majority of pathologists are in small groups**
- **CAP not clear if "data riding" (i.e. relying on the data entries of other EPs or the hospital) is still practical even in large integrated practices in Stage 2**
- **Many pathologists support multiple hospitals and independent practices making it difficult to have sufficient CEHRT**

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PAMA Regulations: Low-Volume/ Expenditure Reporting Exclusion

- **CMS should consider alternative mechanisms to minimize the reporting burden on small laboratories**
  - **Small labs could report:**
    - **Average price reimbursed**
    - **Number of payments for each such test**
  - **Low volume of smaller labs means there is not likely to be significant payment variability**
- **Use Notice and Comment rulemaking to establish the threshold**
  - **Ensures transparency and adequate stakeholder input**

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PAMA Regulations: Exception for Capitated Arrangements

- **Define exception *only* to include global bundled or per-member-per month arrangements in which there is no separately identifiable per service payment**

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PAMA Regulations: Determining "Payment" for a Test

- **Statute does not explicitly define "payment"**
  - **However, payment can be equated to "allowable charges"**
  - **Allowed amount includes patient responsibility**
  - **Assigning coinsurance payments to specific laboratory services can be challenging**
  - **Laboratories are then reporting on what the health plan calculates as "allowable"**
  - **Complex area –includes issues of in-network and out of network and secondary insurance**
- **CMS needs to account for this complexity in its rulemaking**

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PAMA Regulations: Determining Weighted Median

- **Statute requires Medicaid managed care payments to be reported**
  - **Many states statutorily peg Medicaid payments to a percentage of Medicare**
  - **Therefore, simply including Medicaid managed care payments in setting Medicare payments would result in a circular calculation**
  - **Medicare should adjust for this discounting in computing weighted median**

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PAMA Regulations: Civil Monetary Penalties (CMPs)

- **CMPs in law are specified as an "amount of *up to* $10,000 per day for each failure to report or each such misrepresentation or omission"**
  - **Language modeled after drug industry**
    - **Laboratory industry has different economics**
  - **$10,000 per day per test is high penalty**
  - **Ask CMS to calibrate the amount of any penalty to the complexity and impact of the individual reporting**

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PAMA Regulations: Expert Advisory Panel

CMS should appoint pathologists who are experts in:

1. **The fields of molecular pathology**
2. **CPT code assignment**
3. **Laboratory accreditation**

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