



Laboratory Workflow Considerations for
Choosing an HbA1c Methodology:

A Comparative Case Study

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The new language of life

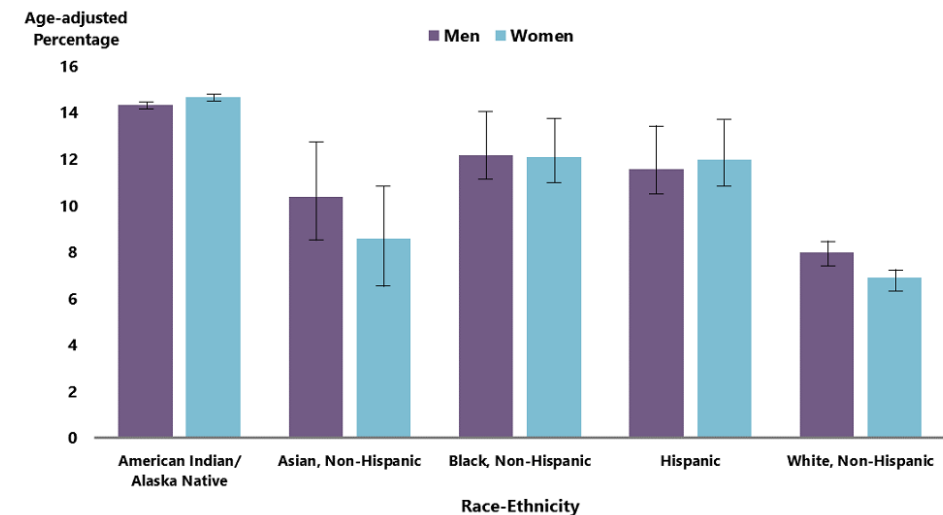
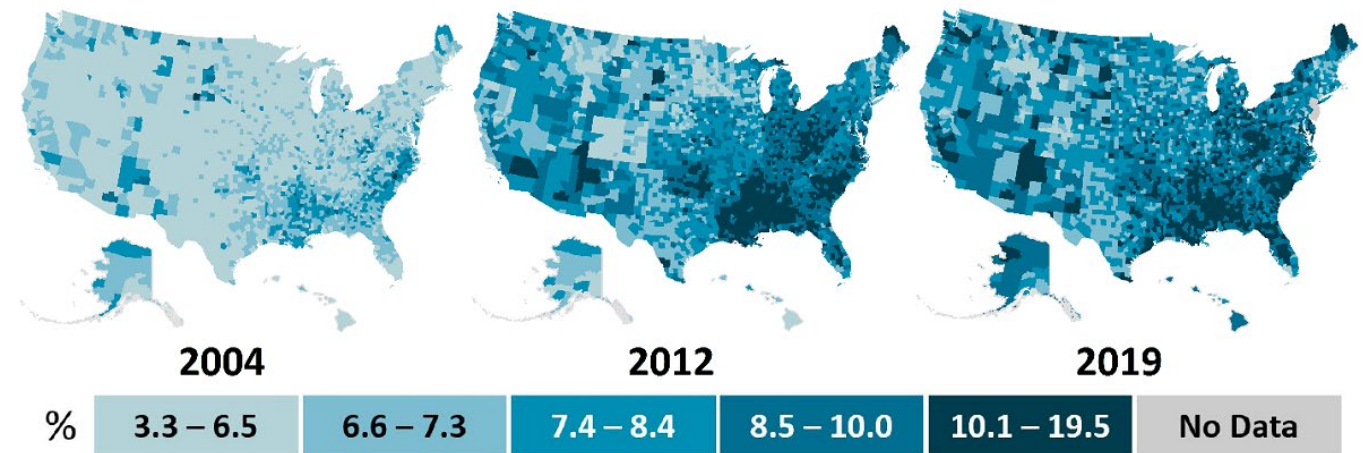
Session Agenda

- Diabetes in the United States
- HbA1c and analytical methodologies
 - Importance of Hemoglobinopathies
- Workflow challenges in clinical laboratories
- Case study introduction / methodology
- Comparative workflow results
- Conclusions
- Sebia's HbA1c Solutions

Diabetes in the USA

Disease State Overview

- **37.3 million** people living with diabetes (**8.5 million** are undiagnosed)
- **96 million** living with prediabetes (38% of adult US population)
- Total direct and indirect costs of diabetes estimated to be **>\$350 billion**
- Prevalence highest among American Indian / Alaska Native populations (14.5%) and Black, non-hispanic (12.1%)



CDC: National Diabetes Statistics Report (2022)

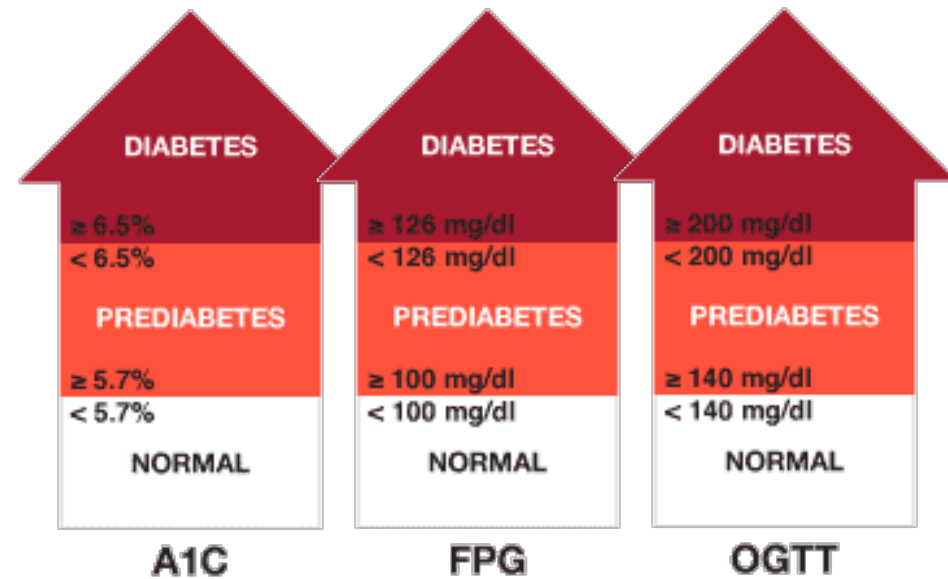
HbA1c and Analytical Methodologies

- Three primary screening / monitoring methodologies:
 1. HbA1c
 2. Fasting Plasma Glucose
 3. Oral Glucose Tolerance Test

Primary HbA1c Methodologies*:

- **Separation:**
 - Capillary Electrophoresis (Sebia)
 - Ion Exchange - HPLC
- **Non-Separation:**
 - Boronate Affinity HPLC**
 - Immunoassay
 - Enzymatic

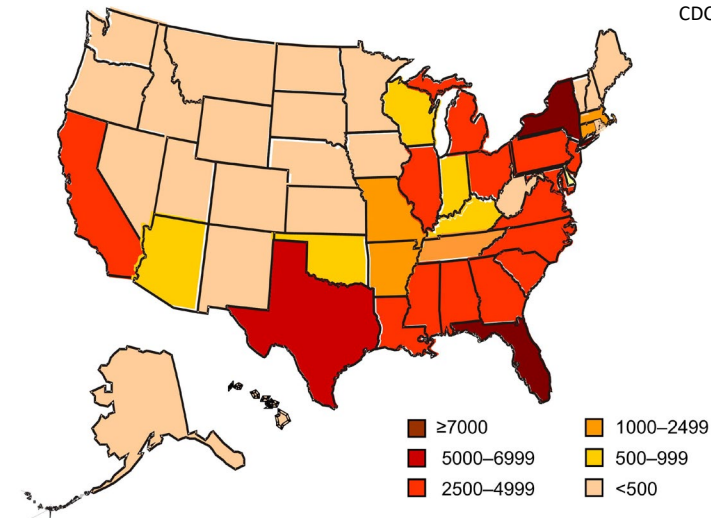
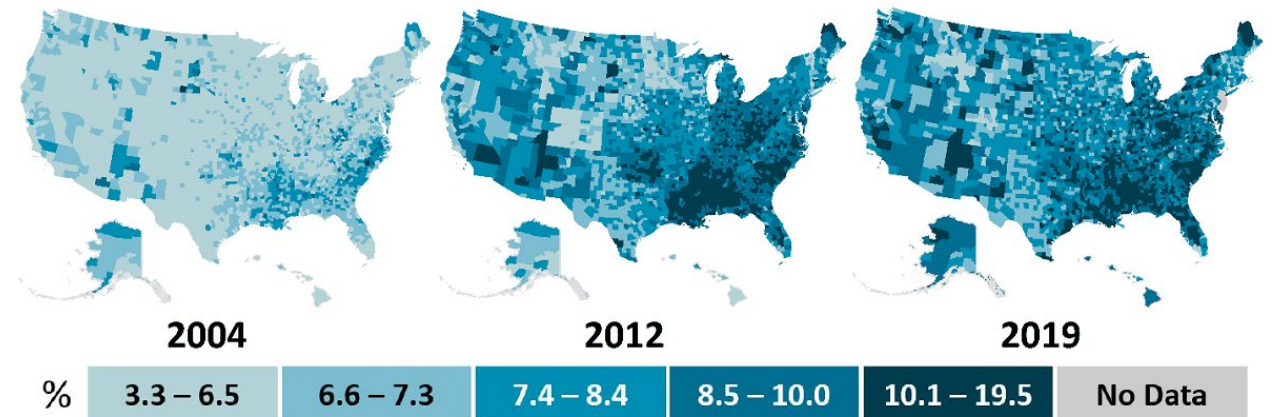
***HbA1c Methods: NGSP Certified**



Diabetes in the USA

Importance of Hemoglobinopathies

- Hemoglobinopathy prevalence **increasing** due to globalization
- Sickle Cell Disease affects **1 in 365** African American babies, with Sickle Cell Trait affecting **1 in 13**
- **Separation methods** are the only HbA1c analytical methods that can **detect hemoglobin variants**
- Hemoglobin variants can **significantly** impact red blood cell lifespan – which will **impact HbA1c % reported**



CDC: US Diabetes Surveillance System (2019)

Hassell, 2009 – Population Estimates of Sickle Cell Disease in the U.S.

Clinical Laboratories

Complex Workflow Challenges



Shared resources across
labs/departments



Increasing test volume
and complexity



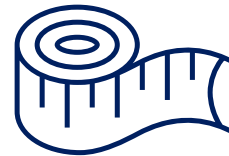
Retention / sourcing
laboratory staff



Complex / Interconnected
systems and networks



Manual processing /
documentation



Constrained / limited
laboratory space



Emphasis on reducing
turn around time

Sebia HbA1c Workflow Study

Introduction

Study Details:

- Conducted at a regional reference laboratory
- Currently running 600 HbA1c tests per day
 - Running on a high-capacity immunoassay system
- Existing Sebia customer for protein testing

Objectives

- Quantify and compare workflow metrics for current state HbA1c methodology vs. (Sebia) future state (including Hands On Time – HOT, maintenance time, manual steps)
- Lab seeking to consolidate assays onto fewer platforms due to staff shortages

Sebia HbA1c Workflow Study

Automation ≠ Hands-Off

- Baseline HOT required for the high-throughput system was significant (425 hours/year)
 - Equivalent to >\$20,000 / year in time spent hands-on with the instrument
- Majority of manual HOT was due to frequent daily/weekly routine maintenance and manual mixing of whole blood specimens
 - Current system does not offer automated mixing

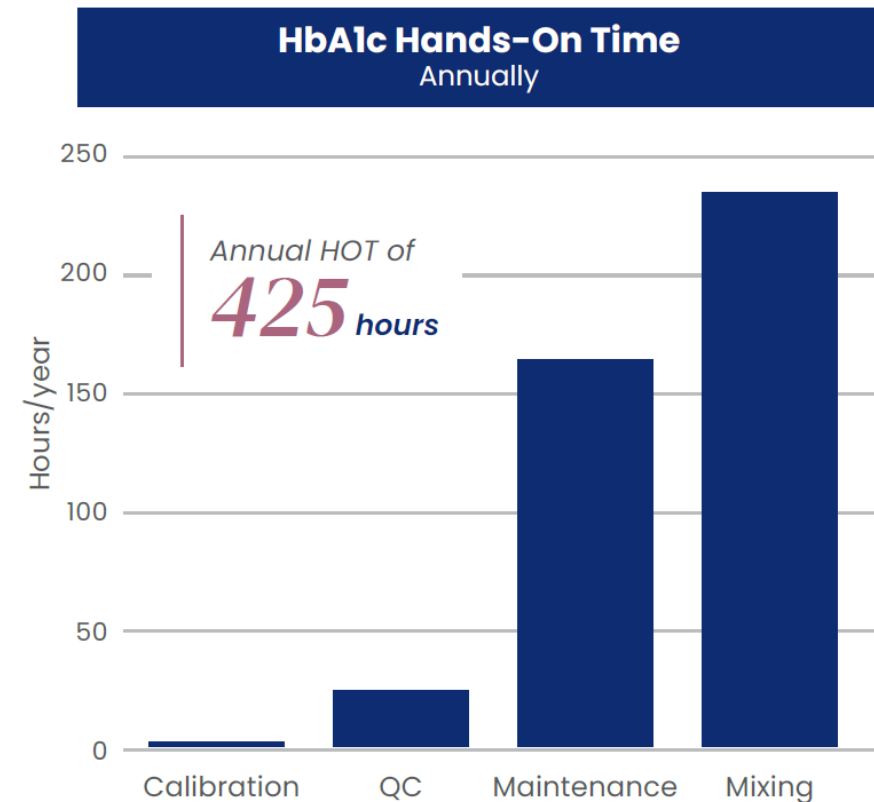
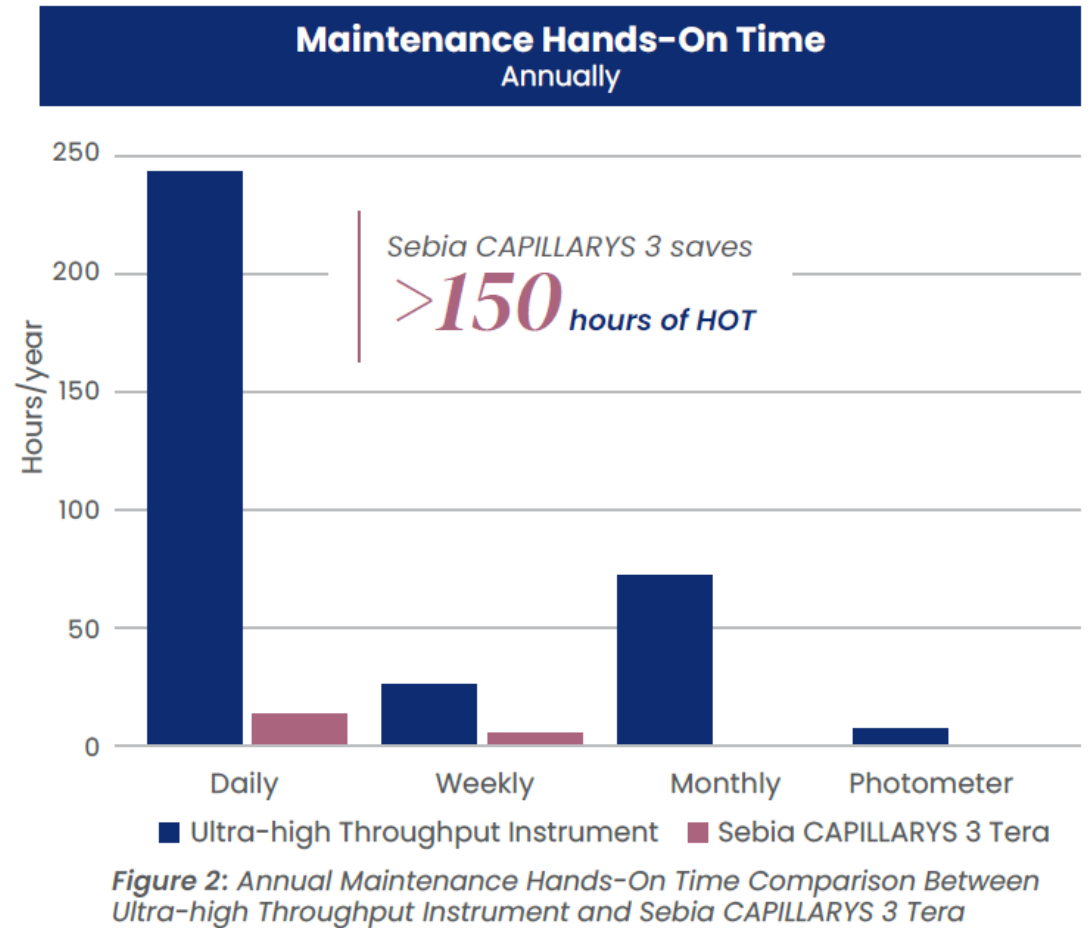


Figure 1: Annual Hands-On Time Required for an Ultra-high Throughput HbA1c Analyzer

Sebia HbA1c Workflow Study

Maintenance Comparison for Annual HOT

- The current method requires significant maintenance at routine intervals, with ~250 hours of HOT per year in daily maintenance alone
- Sebia CAPILLARYS 3 Family of Instruments minimizes both maintenance time and HOT
 - A savings of over 150 hours/year, freeing laboratory staff to focus on value added tasks
- CAPILLARYS 3, pre-schedules routine maintenance: cleaning/decontamination
 - Eliminates need for lab staff to initiate cleaning manually



Sebia HbA1c Workflow Study

Overall Annual HOT Comparison

Across the major components of HOT for this lab (QC, maintenance, and manual mixing), Sebia's solution required significantly less HOT compared to the current solution

- Annual savings of >95% HOT

Conclusions:

- Laboratories conducting HbA1c testing should consider the following when evaluating analytical methods:
 1. HOT required to run/maintain instrument
 2. Workflow impacts – importance of minimizing manual steps
 3. Clinical impact / ability to identify Hb variants

Labs performing even mid size testing should consider looking beyond automation and throughput

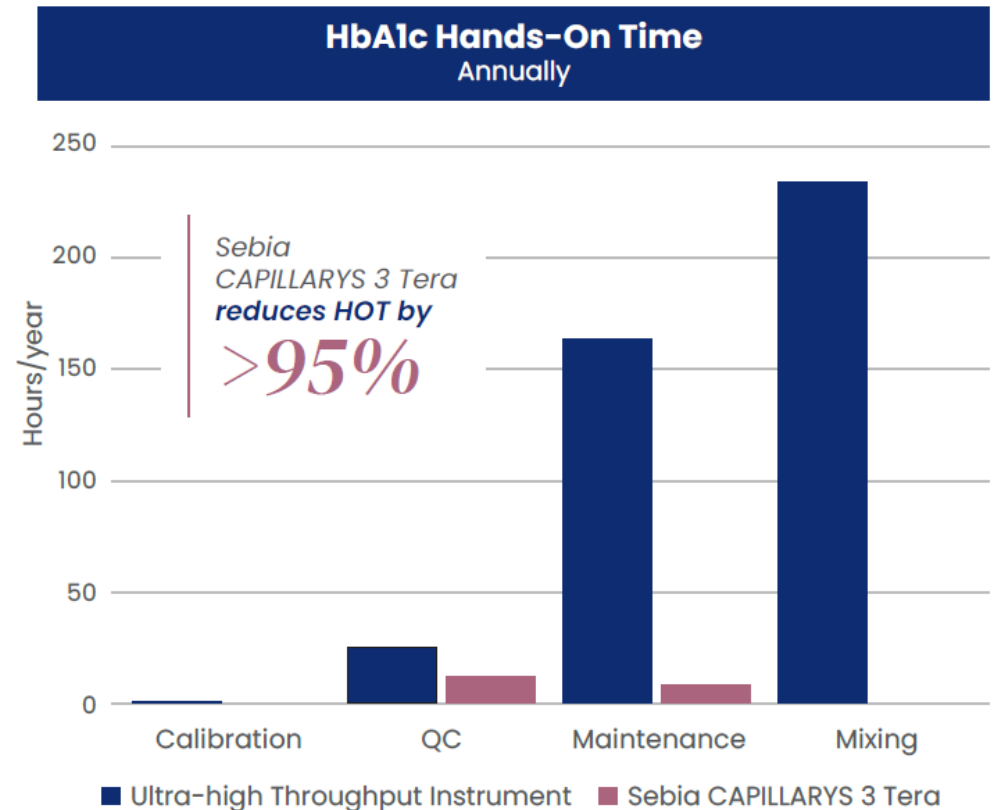


Figure 3: Annual Tasks Requiring Hands-On Time Comparison Between Ultra-high Throughput Instrument and Sebia CAPILLARYS 3 Tera

Sebia Hb Alc:

A fully automated workflow that delivers uncompromised results

Only Capillary Electrophoresis provides the confidence and accuracy of results while detecting variants.

	NGSP/IFCC Certified	Separation Methodology	Detect Hb Variants	Direct IFCC Calculation	β -thalassemia screening*
Immunoassay	●				
Boronate Affinity	●	●			
Ion-exchange HPLC	●	●	●		
Capillary Electrophoresis	●	●	●	●	●

**Sebia enhanced resolution enables detection of the Hb A2 peak, which, if elevated could suggest beta thalassemia*

Sebia HbA1c Solutions

Powered by Capillary Electrophoresis



Fully Automated HbA1c Testing

Simply load racks and walk away.
Reduce hands on labor time



Detection of Hemoglobin Variants

High resolution separation indicating patient
variant status



Easy to Use

No pre-analytical treatment with on-board mixing.
Simply load samples and walk-away



Thank *you.*

sebia 
The new language of life