ATHELAS ONE HGB TRIAL

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01

OBJECTIVES

Determine if the results from the finger prick using the stripe test Athelas One device are comparable with Central Lab results.

02

METHODOLOGY

Multicenter experimental study from Sep 1st - Oct 1st 2020 on 300 healthy/sick patients from USCF, Seattle GH, San Diego GH.

03

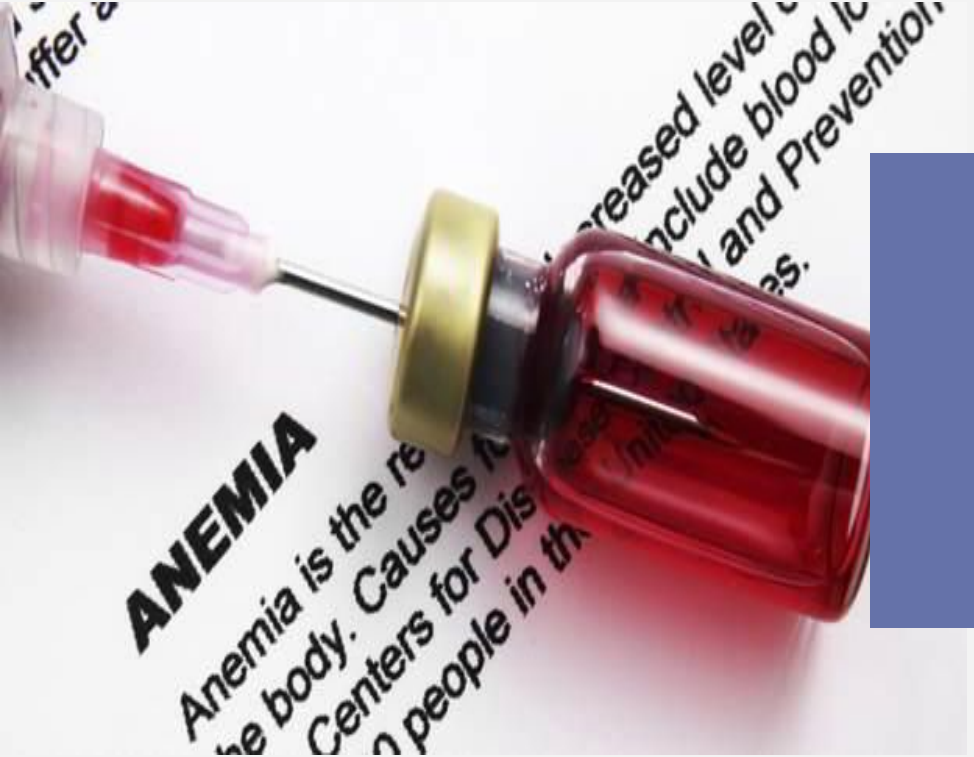
RESULTS ANALYSIS

Overall reproducibility levels were found to meet the acceptance criteria of 3.5% CV for HGB and 7% SD or 3.1 maximum bias for HGB.

04

CONCLUSIONS

Athelas One device is substantially equivalent to the Sysmex XE-5000, Automated Haematology Analyzer in generating HGB parameters.



INTRODUCTION

Hemoglobin (HGB) and Hematocrit (HCT) are blood parameters performed routinely to evaluate the tissues oxygenation. HGB level expressed in grams per deciliter (g/dL) has different levels for males (14-18 g/dL) and females (12-16 g/dL). Anemia, erythrocytosis and abnormal levels of HGB can be diagnosed by available devices in clinical settings with just a small amount of blood and provide results rapidly, but for some setting it's too expensive to access these kind of resources.

HEALTHCARE TODAY

TIME

4 Hrs 7 Mins

average ER Patient WAITING TIME

MONEY

4 Billion/ YEAR

for ER visits

BACKGROUND

Cost of blood testing USA - $22.53 B
Waiting for test results: Hours -->Days, that impacts the life of patients living with chronic diseases.

NEED

An integrative way to count your WBC, quickly, painless, accurate and get the results in a manner amount of time.

CLINICAL TRIAL

Run a multicenter clinical trial in 1 month, on 300 patients healthy and sick.

Athelas

Medical device that use computer vision and deep learning to make your diagnostic lab test available in your own setting.

GOALS

RESEARCH

Have clinical measurable data to prove that Athelas One device is comparable with the devices on the market.

DEVELOPMENT

Computer vision and Deep Learning software that measure accurately levels of HGB and Ht from Blood samples.

RESULTS

Accuracy of the results generated by capillary fingerstick blood on the Athelas device versus venous blood on the Sysmex XE -5000.

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METHODS

SITES & OPERATORS

Multicenter (3 hospitals)
3 investigators -3 nurses

INFRASTRUCTURE

2 devices for every site

SUBJECTS

290 subjects between age 21-90, males & females

STATISTICS

ANOVA analysis, mean, SD, CV, Passing-Bablock regression.

BEFORE CLINICAL TRIAL

- Site choosing
- I, training
- Athelas One, Symvex XE-5000
- Database
- Biostatistician

by Athelas One

-I: Form FDA 1572 , CV, financial stat.
- Study Protocol: Signature page
-IDB signature page
-IRB/IEC approval letter
-Central Lab certif and n. ranges.
-Ethics review and approved
-Sign the budget and contract

by Athelas One & I

- Pre-Study Visit: data of visit agreement between CRA + paper to sign during the visit.
- IDE application for FDA

by Athelas One & CRA

ELIGIBILITY

INCLUSION

- 1. Informed Consent
- 2. Compliance and availability for the duration of the study
- 3. M/F aged 21-90
- 4. Healthy or diagnosed with cancer or hematologic diseases.
- 5. Women of reproductive potential must be on HEC.
- 6. Men of reproductive potential must use condoms.
- 7. US citizen/ permanent resident
-

EXCLUSION

1. Any disease that would put patient's health at risk: severe thrombocytopenia, severe allergies.
2. Any patient with COVID19+ test.
3. M/F aged < 21 & >90.
4. Use of disallowed concomitant medications.
5. Febrile illness that precludes or delays participation (past 12 hours)
6. Pregnancy or lactation.
7. Known allergic reactions to components of the study product(s).

RECRUITMENT

1. Avoid specifying unnecessarily restrictive inclusion and exclusion criteria.
2. Necessary recruitment budget for start-up training, advertising, staff time, etc.
3. Review recruitment rates, dropout rates, and screening success rates from previous studies.
4. Develop a system to track the number of participants enrolled per recruiter per site.

CLINICAL TRIAL

PRECLINICAL

Athelas One - Lab studies

PHASE 1

Human Safety

PHASE 2

Expanded Safety

PHASE 3

Efficacy & Safety

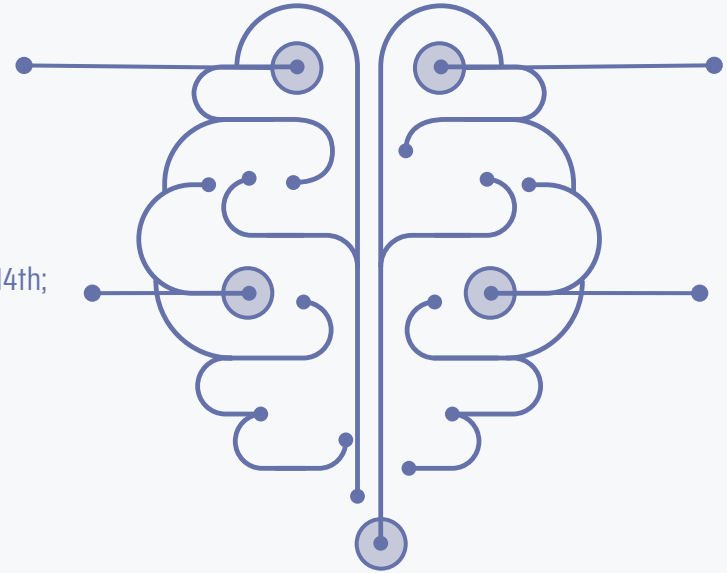
TRIAL TIMELINE

WEEK 1

SIV, patients IC and enrollment; Data collection for 1st week + AE and reconciliation.

WEEK 2

Data Collection + verification - day 14th; Report AE, CM, subject withdrawal.



WEEK 3

Get all the data from the lab and devices, sites, all necessary documents.

WEEK 4

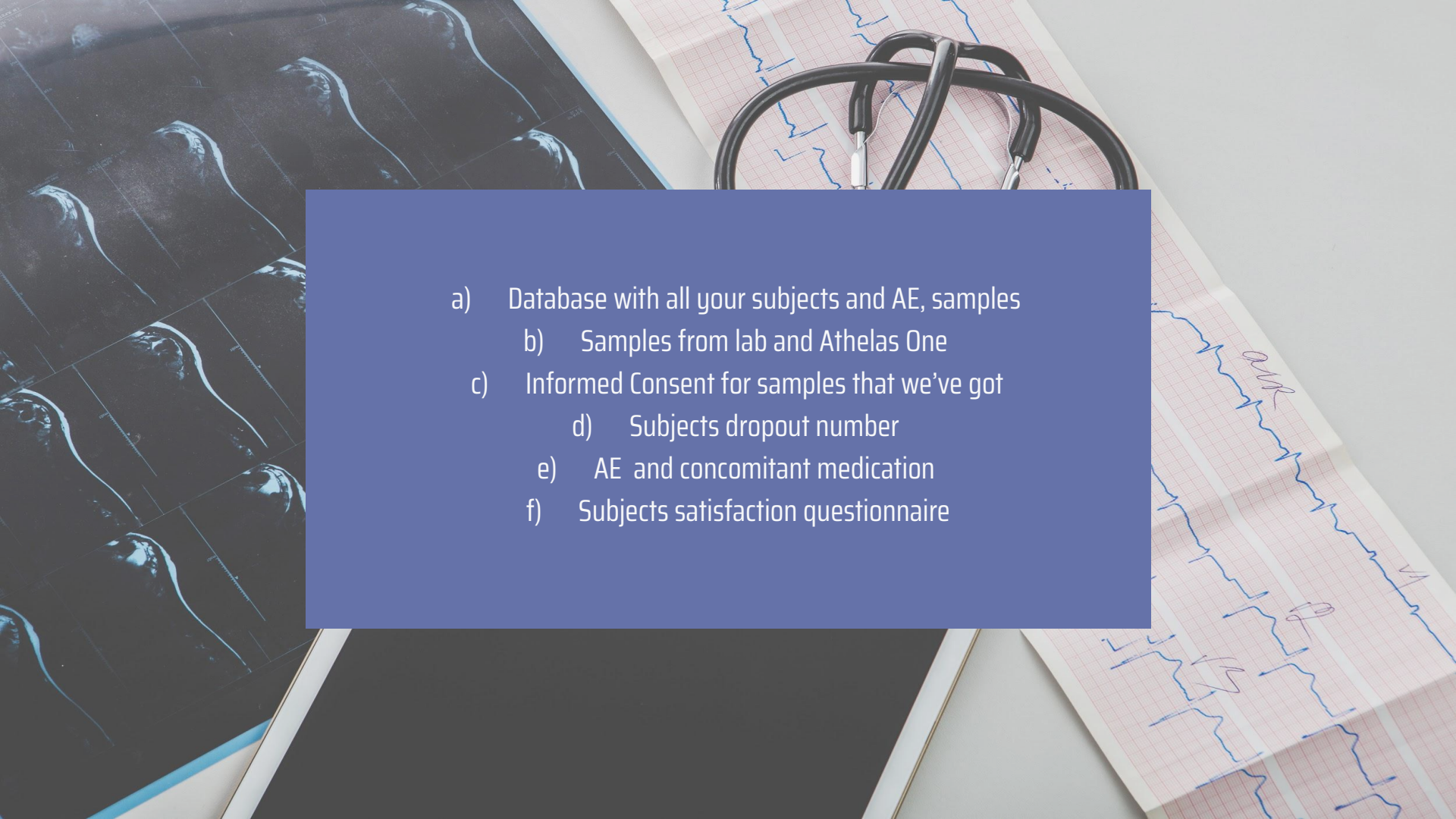
Data analysis and database lock; Subject follow-up and referral in case they need it.

RESULTS

Analyse and compare data from Athelas One device with gold standard.

TRIAL DATA OVERVIEW

Visits/ assessments	Screening 1 (days -28 to -2)	Baseline 2 (day -1)	Visit 1 101 (day 1)	Visit 2 102 (day 7)	Visit 3 103 (day 14)	End of study 199 (day 28)
Informed consent	X					
Inclusion/ Exclusion Criteria	X	X				
AE/SAE	X	X	X	X	X	X
Concomitant medications	X	X	X	X	X	X
Surgical and medical procedures	X	X	X	X	X	X
Demography	X					
Vital signs	X	X	X	X	X	X
Body height	X					
Blood draw with device	X	X	X	X	X	X
Blood draw for Central lab cover page	X	X	X	X	X	X
Medical History/ current medical conditions	X					



a) Database with all your subjects and AE, samples

b) Samples from lab and Athelas One

c) Informed Consent for samples that we've got

d) Subjects dropout number

e) AE and concomitant medication

f) Subjects satisfaction questionnaire

FACTORS TO CONSIDER

Enrollment and informed consent for 300 patients

SUBJECTS

6 Athelas One devices, 3 POC, 6 symvex devices

INFRASTRUCTURE

Missing data, Error data due to device misusing.

EDUCATION

FACTORS TO CONSIDER

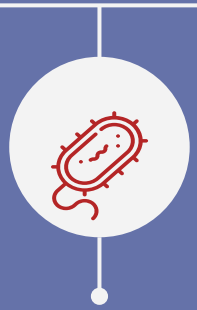
Sickle cell anemia
B Thalassemia

HGB TYPES

Old, females,
pregnancy, kids,
black - lower levels

AGE/RACE

Low amount of blood
on the stripe;
Calibration



AGENTS

METHODOLOGY

West Coast USA inpatients and recruited subjects

280 subjects

Subject -2 interv - 21 days
Samples collected daily and uploaded in the CDB;

3 WEEKS
Experimentation time

GOAL
Compare blood results: predicate & Athelas One

RESULTS

A total of 84 readings were generated at each site for each level of control. Overall reproducibility levels were found to meet the acceptance criteria of 3.5% CV for HGB and 7% SD or 3.1 maximum bias for HGB

POSSIBLE ERRORS

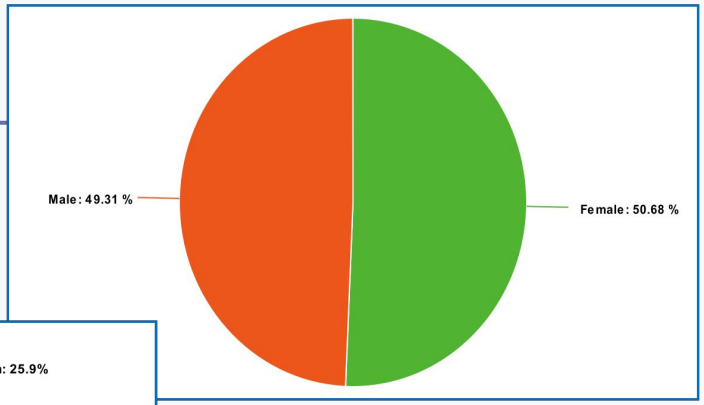
Data collection error; less samples than expected; device error;

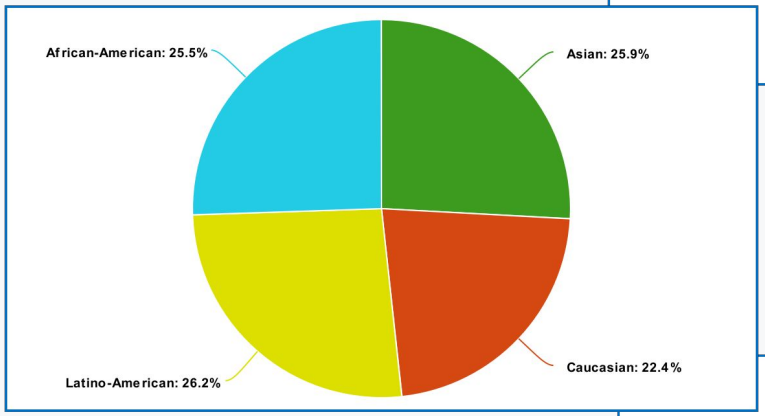
RESULTS

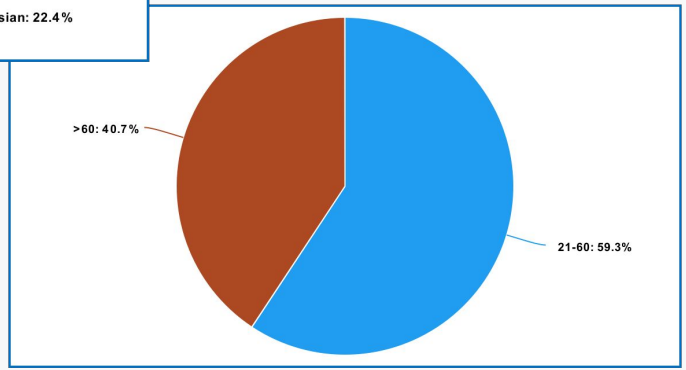
1	Subject	Gender	Clinical Site	Age	Disease	Concomite	AE		Race
2							Type	Date	
3	1	M	1001	21	Healthy	NO	NO		Asian
4	2	F	1001	23	Healthy	NO	NO		Caucasian
5	3	F	1003	65	BC	Chemo	Bleeding		Asian
6	4	F	1002	56	BC	Chemo	NO		Latino
7	5	M	1001	67	CRC	Chemo	No		African American
8	6	F	1003	87	CC	Chemo	Rush		African American
9	7	F	1002	45	BC	Chemo	NO		Latino
10	8	F	1001	56	BC	Chemo	NO		African American
11	9	F	1001	43	Healthy	NO	Fainting		Latino
12	10	F	1002	67	CRC	Chemo	NO		Latino
13	11	M	1001	24	RC	Chemo	NO		Asian
14	12	M	1003	65	CRC	Chemo	NO		Asian
15	13	M	1003	35	Healthy	NO	Rush		Asian
16	14	M	1001	75	CC	Chemo	Hematom		Latino
17	15	M	1001	35	CC	Chemo	NO		Caucasian
18	16	M	1001	75	CRC	Chemo	NO		Caucasian
19	17	M	1001	75	RC	Chemo	Rush		Latino
20	18	M	1001	73	RC	Chemo	NO		African American
21	19	M	1001	45	Healthy	NO	NO		Caucasian
22	20	M	1001	57	Healthy	NO	Rush		Caucasian
23	21	F	1001	24	Healthy	NO	NO		Asian
24	22	F	1002	40	Healthy	NO	NO		Caucasian
25	23	F	1002	43	BC	Chemo	Bleeding		Asian
26	24	M	1002	56	LC	Chemo	Hematom		Asian
27	25	M	1002	78	LC	Chemo	NO		African American
28	26	F	1002	35	BC	Chemo	NO		African American
29	27	M	1002	25	BC	Chemo	NO		Latino
30	28	F	1002	57	CC	Chemo	NO		African American
31	29	M	1002	66	RC	Chemo	No		Caucasian

TENDENCY

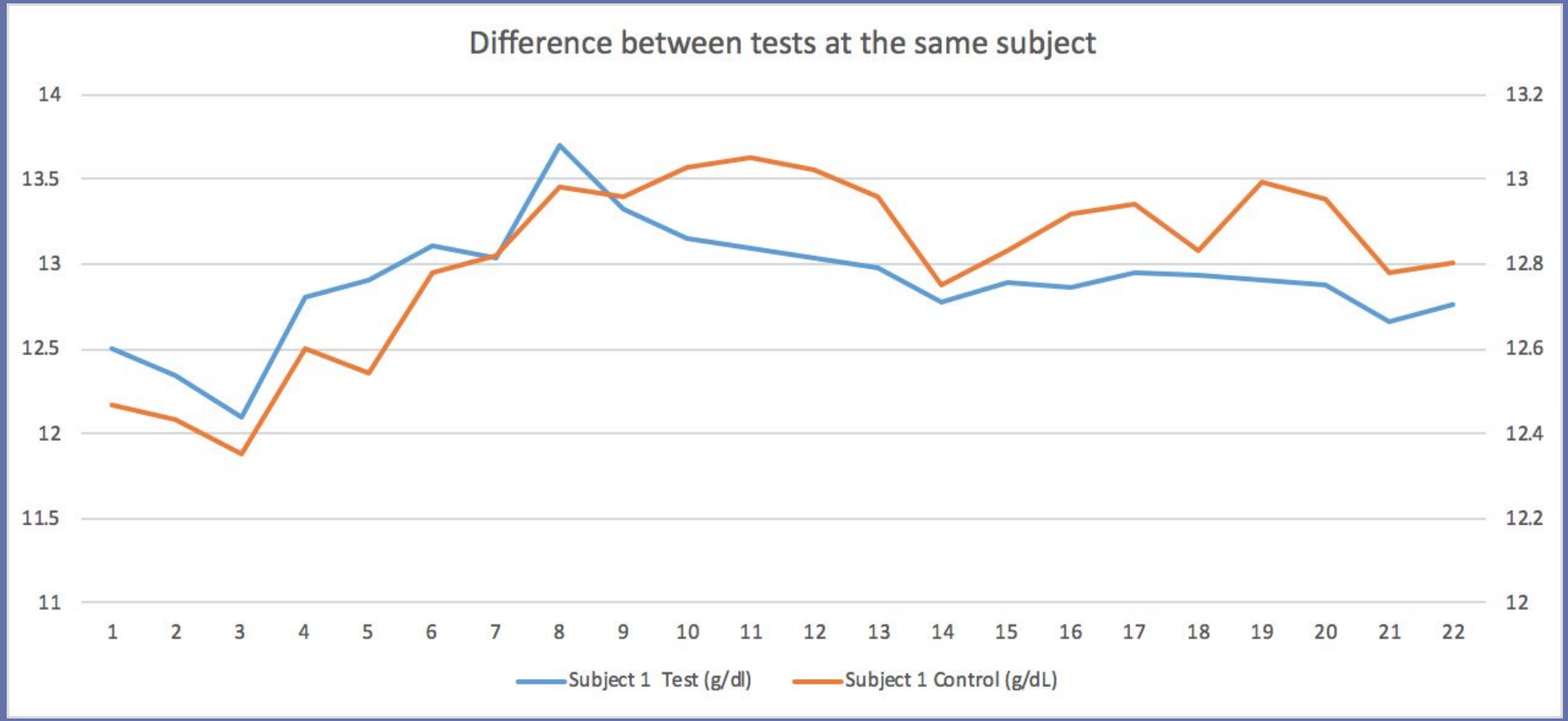
Distributed data between races, gender and age.



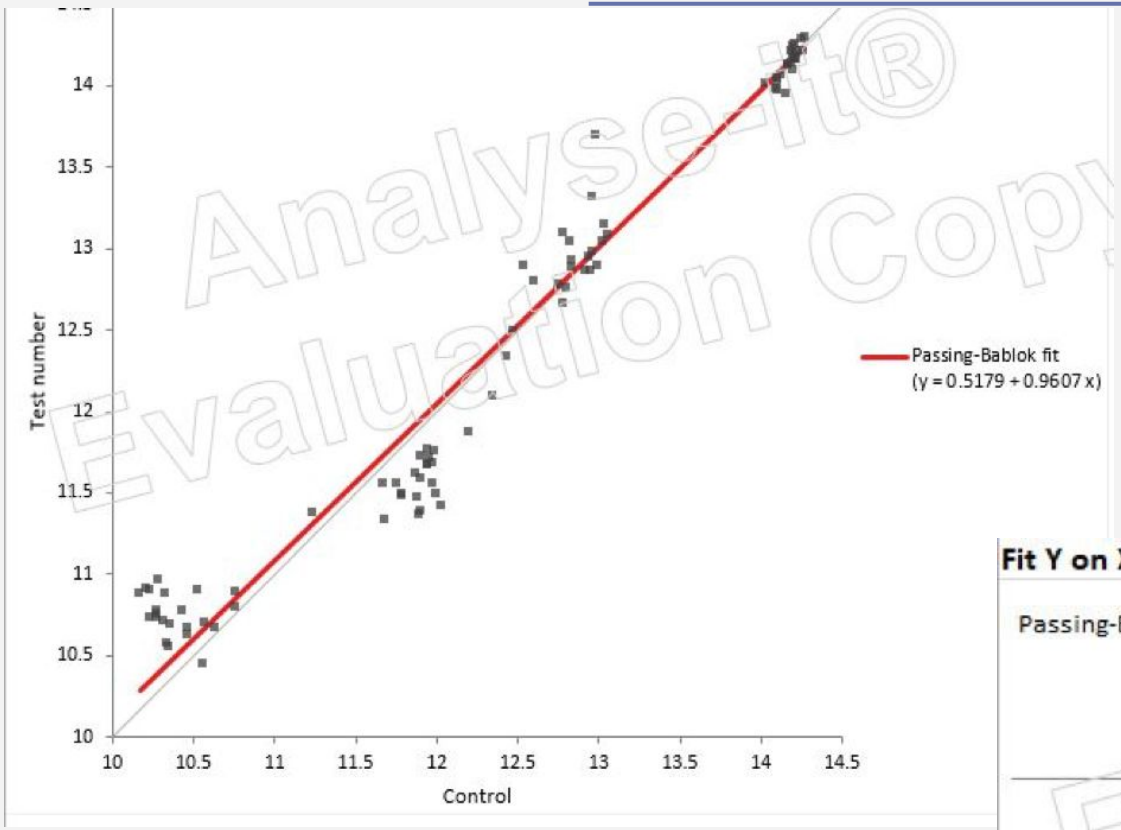




RESULTS


Difference between tests at the same subject
14
13.5
13
12.5
12
11.5
11
13.2
13
12.8
12.6
12.4
12.2
12
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
Subject 1 Test (g/dl)
Subject 1 Control (g/dL)

RESULTS ANALYSIS



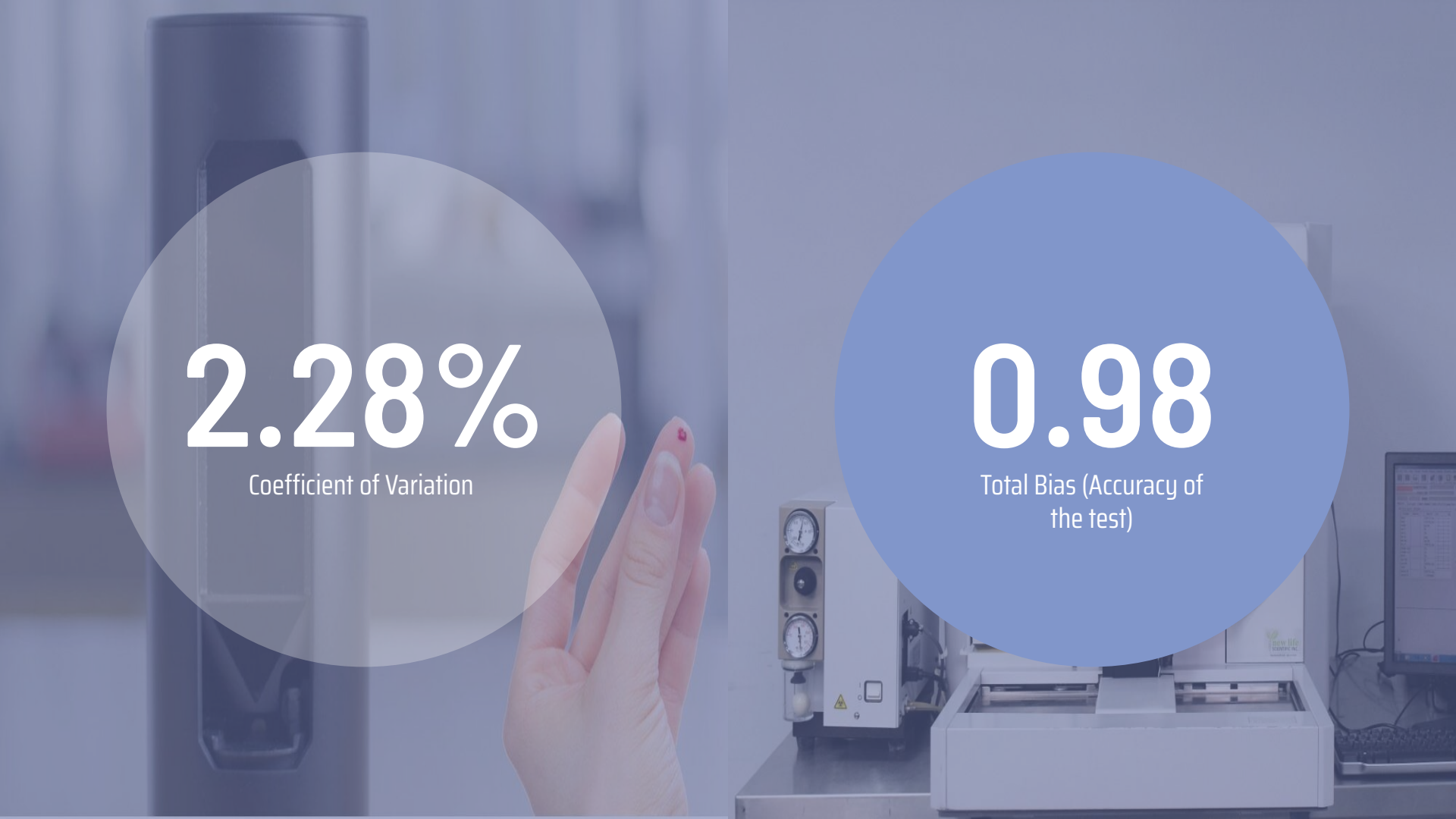
PASSING -BABLOK Regression

Fit Y on X

Passing-Bablok fit

Equation	Test number = 0.5179 + 0.9607 Control

Parameter	Estimate	95% CI
Intercept	0.5179	-0.3510 to 1.012
Slope	0.9607	0.9233 to 1.024



2.28%

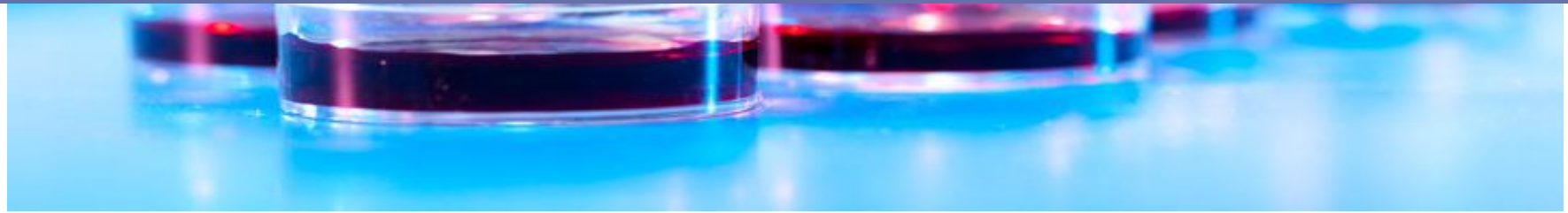
Coefficient of Variation

0.98

Total Bias (Accuracy of the test)

CONCLUSIONS

The study found that the Athelas One device is substantially equivalent to the Sysmex XE-5000, Automated Haematology Analyzer in generating HGB parameters.



THANKS

Does anyone have any questions?

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DATABASE

- Subject: Age, Gender, Race
- Lab type: Central, Symvex & Athelas One

Variable label	Variable name	Format	Length	Mandatory	Example
Study Identifier	STUDYID	Char	20	Y	Athelas One, hemoglobin analyzer
Subject Identifier	SUBJID	Number	7	Y	1001001
Visit name	VISIT	Char	20	Y	Screening
Visit number	VISITNUM	Number	3	Y	1
Specimen ID	LBID	Number	10	Y	1234567890
Date of examination	LBDT	Date	9	Y	09.01.2020
Time of specimen collection	LBTM	Time	5	Y	10:07 PDT
Lab test name	LBTEST	Char	40	Y	Hemoglobin
Lab test short name	LBTESTSH	Char	5	Y	HGB
Result in central lab units	LBRES	Char	40	Y	14
Central lab unit	LBUNIT	Char	40	Y	g/dL
Reference range lower limit	LBLOW	Char	40	Y	7
Reference range upper limit	LBHIGH	Char	40	Y	21
Reference range indicator central lab	LBIND	Char	40	N	Blank = normal, H = high, L = low
Specimen condition	LBSPEC	Char	40	N	Available/destroyed