ATHELAS | Portable Diagnostics through Deep Learning and Computer Vision

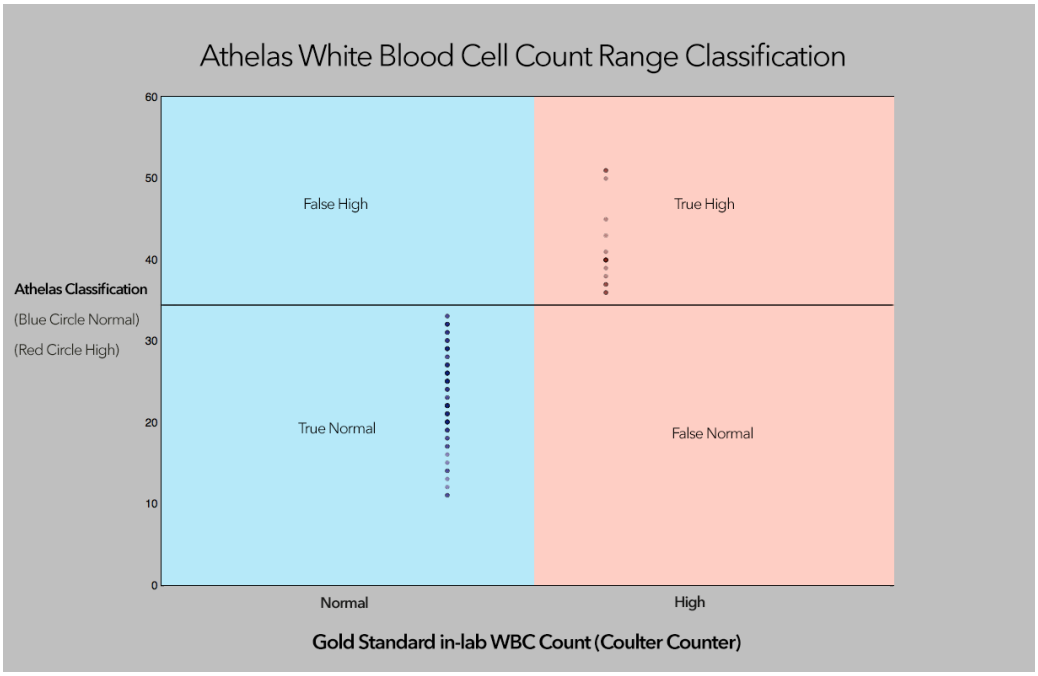
Clinical Accuracy: Dataset 1 - WBC

In clinical validations, the Athelas device has achieved 100% Clinical Range accuracy for White Blood Cell Counts.

The trial was conducted across patients in a clinical setting at FEMAP Hospital.

For usage - a drop of blood is taken from a patient's fingertip and placed on the small test strip. The strip is inserted into the low-cost, portable device, and a few moments later a White Blood Cell is produced on the app, on screen, or via email.

Below is the 100 patient sample set showcasing the WBC ranges correctly classified by Athelas in comparison to existing gold standards (in-lab machines) in the following segments: **Normal** (4.5-10k WBC/uL), **High** (10k+ WBC/uL)

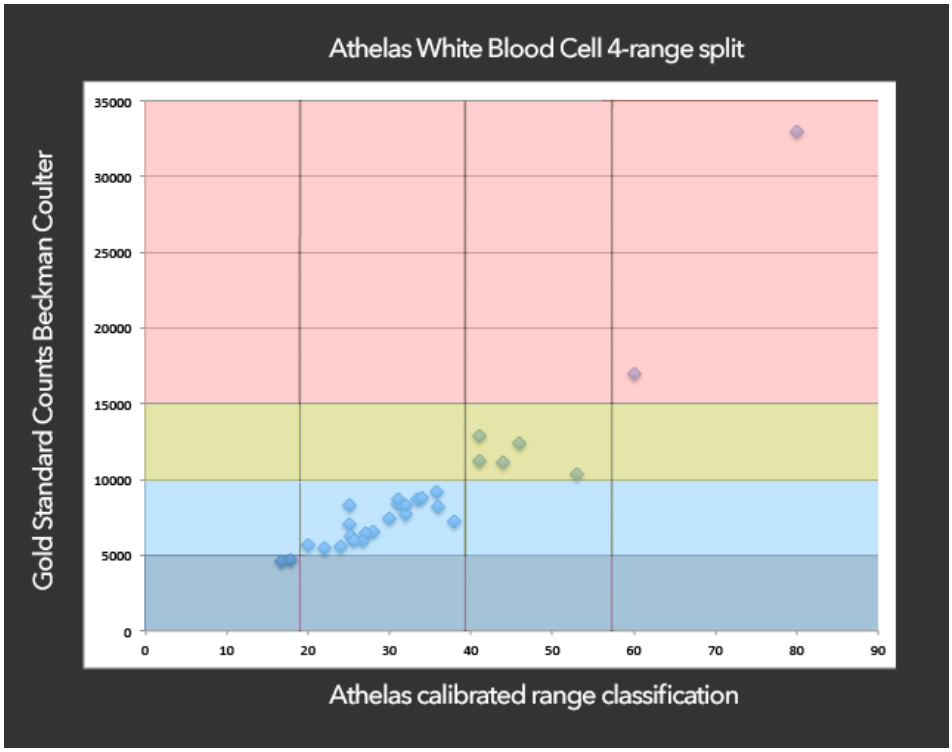


Each point above represents a single clinical patient, the x-axis showcases the split between Normal WBC counts and High as recorded by the in-lab, gold standard counter (Blue Region and Red Region). The y-axis shows the Athelas split: red circles mean the device has registered as **High**, while blue indicates **Normal** range – the dividing line is the Athelas boundary (10k/ uL WBC) for the two classes. As indicated by the class boundary, the system successfully captures 100% of the ranges accurately with a 0% false positive/negative error rate in the normal vs. high clinical WBC classification.

In the given clinical study, no patients were found in the **Low** WBC range (less than 4.5k WBC/uL), but in bench studies, the device has been capable of correctly classifying this range as well while maintaining the same degree of accuracy. **Very high** counts (greater than 15k WBC/uL) are also separately flagged by the system as potential presence of malignancies and Leukemia (as a sub-group of the **High** category).

The generated WBC Counts from Athelas are used to identify and flag infection, inflammation, allergic reactions, or viral conditions within seconds at Point of Care. Current deployments of the device are aimed to be placed in waiting rooms, doctor's offices, and Urgent Care facilities to quickly flag conditions needing immediate response.

Below is the 4-class split range classification by the Athelas system across the same dataset:



The Athelas device also generates Red Blood Cell Counts, White Blood Cell Differentials, and Hematocrit values, along with Urine Tract Infection (UTI) or Pyuria diagnostics from a drop of urine fluid - which will all be rolled out to users in the coming months.

Furthermore, precision studies, environmental studies, aging studies, and re-concentration studies were conducted at various edge-cases (especially in the lower concentration ranges, of which our clinical study had fewer data points) to indicate the system's performance. Below is a summary of those tests (range 1: lower than 4500, range 2: between 4500 and 10000, range 3: greater than 10000).

Testing in Different Environment/ Temperatures

1. (Concentration = 2K/uL)		t= 7-10 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	1	1	1	1
2	1	1	1	1
3	1	1	1	1
4	1	1	1	1
5	1	1	1	1
2. Concentration = 4k/uL		t=7-15 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	1	1	1	1
2	1	1	1	1
3	1	1	1	1
4	1	1	1	1
5	1	1	1	1
3. Concentration = 5.5k/uL		t=7-15 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	2	2	2	2
2	2	2	2	2
3	2	2	2	2
4	2	2	2	2
5	2	2	2	2
4. Concentration = 9k/uL		t=7-15 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	2	2	2	2
2	2	2	2	2
3	2	2	2	2
4	2	2	2	2

5	2	2	2	2
5. Concentration = 11k/uL		t=7-15 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3
6. Concentration = 15k/uL		t=7-15 minutes		
Sample	Fridge	Outside	Outside	Inside (room temp)
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3
7. Concentration = 22k/ul				
Sample	Fridge	Outside	Outside	Inside (room temp)
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3

Testing Range
Accuracy/Precision

1. (Concentration = 2K/uL)	
Sample Number	Range
1	1
2	1
3	1
4	1
5	1
6	1
7	1
8	1
9	1
10	1
11	1

12	1
13	1
14	1
15	1
16	1
17	1
18	1
19	1
20	1

2. (Concentration = 4K/ul)

Sample Number	Range
1	1
2	1
3	1
4	1
5	1
6	1
7	1
8	1
9	1
10	1
11	1
12	1
13	1
14	1
15	1
16	1
17	1
18	1
19	1
20	1

3. (Concentration = 5.5K/ul)

Sample Number	Range
1	2
2	2
3	2
4	2
5	2
6	2
7	2
8	2

9	2
10	2
11	2
12	2
13	2
14	2
15	2
16	2
17	2
18	2
19	2
20	2

4. Concentration = 9K/uL

Sample Number	Range
1	2
2	2
3	2
4	2
5	2
6	2
7	2
8	2
9	2
10	2
11	2
12	2
13	2
14	2
15	2
16	2
17	2
18	2
19	2
20	2

5. Concentration = 11K/ul

Sample Number	Range
1	3
2	3
3	3
4	3
5	3

6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

6. Concentration = 15K/ul

Sample Number	Range
1	3
2	3
3	3
4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

7. Concentraton = 22K/ul

Sample Number	Range
1	3
2	3

3	3
4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

Testing Aging over time

1. (Concentration = 2K/uL)		T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	1	1	1	1
2	1	1	1	1
3	1	1	1	1
4	1	1	1	1
5	1	1	1	1
6	1	1	1	1
7	1	1	1	1
8	1	1	1	1
9	1	1	1	1
10	1	1	1	1
11	1	1	1	1
12	1	1	1	1
13	1	1	1	1
14	1	1	1	1
15	1	1	1	1
16	1	1	1	1
17	1	1	1	1
18	1	1	1	1
19	1	1	1	1
20	1	1	1	1

2. (Concentration = 4K/ul)		T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	1	1	1	1
2	1	1	1	1
3	1	1	1	1
4	1	1	1	1
5	1	1	1	1
6	1	1	1	1
7	1	1	1	1
8	1	1	1	1
9	1	1	1	1
10	1	1	1	1
11	1	1	1	1
12	1	1	1	1
13	1	1	1	1
14	1	1	1	1
15	1	1	1	1
16	1	1	1	1
17	1	1	1	1
18	1	1	1	1
19	1	1	1	1
20	1	1	1	1

3. (Concentration = 5.5K/ul)		T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	2	2	2	2
2	2	2	2	2
3	2	2	2	2
4	2	2	2	2
5	2	2	2	2
6	2	2	2	2
7	2	2	2	2
8	2	2	2	2
9	2	2	2	2
10	2	2	2	2
11	2	2	2	2
12	2	2	2	2
13	2	2	2	2
14	2	2	2	2
15	2	2	2	2
16	2	2	2	2
17	2	2	2	2

18	2	2	2	2
19	2	2	2	2
20	2	2	2	2

4. Concentration = 9K/uL	T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	2	2	2	2
2	2	2	2	2
3	2	2	2	2
4	2	2	2	2
5	2	2	2	2
6	2	2	2	2
7	2	2	2	2
8	2	2	2	2
9	2	2	2	2
10	2	2	2	2
11	2	2	2	2
12	2	2	2	2
13	2	2	2	2
14	2	2	2	2
15	2	2	2	2
16	2	2	2	2
17	2	2	2	2
18	2	2	2	2
19	2	2	2	2
20	2	2	2	2

5. Concentration = 11K/ul	T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3
6	3	3	3	3
7	3	3	3	3
8	3	3	3	3
9	3	3	3	3
10	3	3	3	3
11	3	3	3	3
12	3	3	3	3
13	3	3	3	3
14	3	3	3	3
15	3	3	3	3
16	3	3	3	3

17	3	3	3	3
18	3	3	3	3
19	3	3	3	3
20	3	3	3	3

6. Concentration = 15K/ul		T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3
6	3	3	3	3
7	3	3	3	3
8	3	3	3	3
9	3	3	3	3
10	3	3	3	3
11	3	3	3	3
12	3	3	3	3
13	3	3	3	3
14	3	3	3	3
15	3	3	3	3
16	3	3	3	3
17	3	3	3	3
18	3	3	3	3
19	3	3	3	3
20	3	3	3	3

7. Concentraton = 22K/ul		T = (7-10 minutes)	T = 1 hour	T = 2 hour
1	3	3	3	3
2	3	3	3	3
3	3	3	3	3
4	3	3	3	3
5	3	3	3	3
6	3	3	3	3
7	3	3	3	3
8	3	3	3	3
9	3	3	3	3
10	3	3	3	3
11	3	3	3	3
12	3	3	3	3
13	3	3	3	3
14	3	3	3	3
15	3	3	3	3

16	3	3	3	3
17	3	3	3	3
18	3	3	3	3
19	3	3	3	3
20	3	3	3	3

Testing Accuracy/Precision after takedown and reconfiguration

Setup at t=0		**Setup and recalibration at t=2 hours**	
1. (Concentration = 2K/uL)			
Sample Number	Range	Sample Number	Range
1	1	1	1
2	1	2	1
3	1	3	1
4	1	4	1
5	1	5	1
6	1	6	1
7	1	7	1
8	1	8	1
9	1	9	1
10	1	10	1
11	1	11	1
12	1	12	1
13	1	13	1
14	1	14	1
15	1	15	1
16	1	16	1
17	1	17	1
18	1	18	1
19	1	19	1
20	1	20	1
Setup at t=0		**Setup and recalibration at t=2 hours**	
2. (Concentration = 4K/ul)		Sample Number	Range
Sample Number	Range	1	1
1	1	2	1
2	1	3	1
3	1	4	1
4	1	5	1
5	1	6	1
6	1	7	1
7	1	8	1
8	1	9	1

9	1	10	1
10	1	11	1
11	1	12	1
12	1	13	1
13	1	14	1
14	1	15	1
15	1	16	1
16	1	17	1
17	1	18	1
18	1	19	1
19	1	20	1
20	1		

Setup at t=0 3. (Concentration = 5.5K/ul)		Setup and recalibration at t=2 hours	
Sample Number	Range	Sample Number	Range
1	2	1	2
2	2	2	2
3	2	3	2
4	2	4	2
5	2	5	2
6	2	6	2
7	2	7	2
8	2	8	2
9	2	9	2
10	2	10	2
11	2	11	2
12	2	12	2
13	2	13	2
14	2	14	2
15	2	15	2
16	2	16	2
17	2	17	2
18	2	18	2
19	2	19	2
20	2	20	2

Setup at t=0 4. Concentration = 9K/uL		Setup and recalibration at t=2 hours	
Sample Number	Range	Sample Number	Range
1	2	1	2
2	2	2	2
3	2	3	2
4	2	4	2
5	2	5	2
		6	2

6	2	7	2
7	2	8	2
8	2	9	2
9	2	10	2
10	2	11	2
11	2	12	2
12	2	13	2
13	2	14	2
14	2	15	2
15	2	16	2
16	2	17	2
17	2	18	2
18	2	19	2
19	2	20	2
20	2		

5. Concentration = 11K/ul		Setup and recalibration at t=2 hours	
Sample Number	Range	Sample Number	Range
1	3	1	3
2	3	2	3
3	3	3	3
4	3	4	3
5	3	5	3
6	3	6	3
7	3	7	3
8	3	8	3
9	3	9	3
10	3	10	3
11	3	11	3
12	3	12	3
13	3	13	3
14	3	14	3
15	3	15	3
16	3	16	3
17	3	17	3
18	3	18	3
19	3	19	3
20	3	20	3

6. Concentration = 15K/ul		Setup and recalibration at t=2 hours	
Sample Number	Range	Sample Number	Range
1	3	1	3
2	3	2	3
3	3	3	3

4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

7. Concentraton = 22K/ul	
Sample Number	Range
1	3
2	3
3	3
4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3

Setup and recalibration at t=2 hours	
Sample Number	Range
1	3
2	3
3	3
4	3
5	3
6	3
7	3
8	3
9	3
10	3
11	3
12	3
13	3
14	3
15	3
16	3
17	3
18	3
19	3
20	3