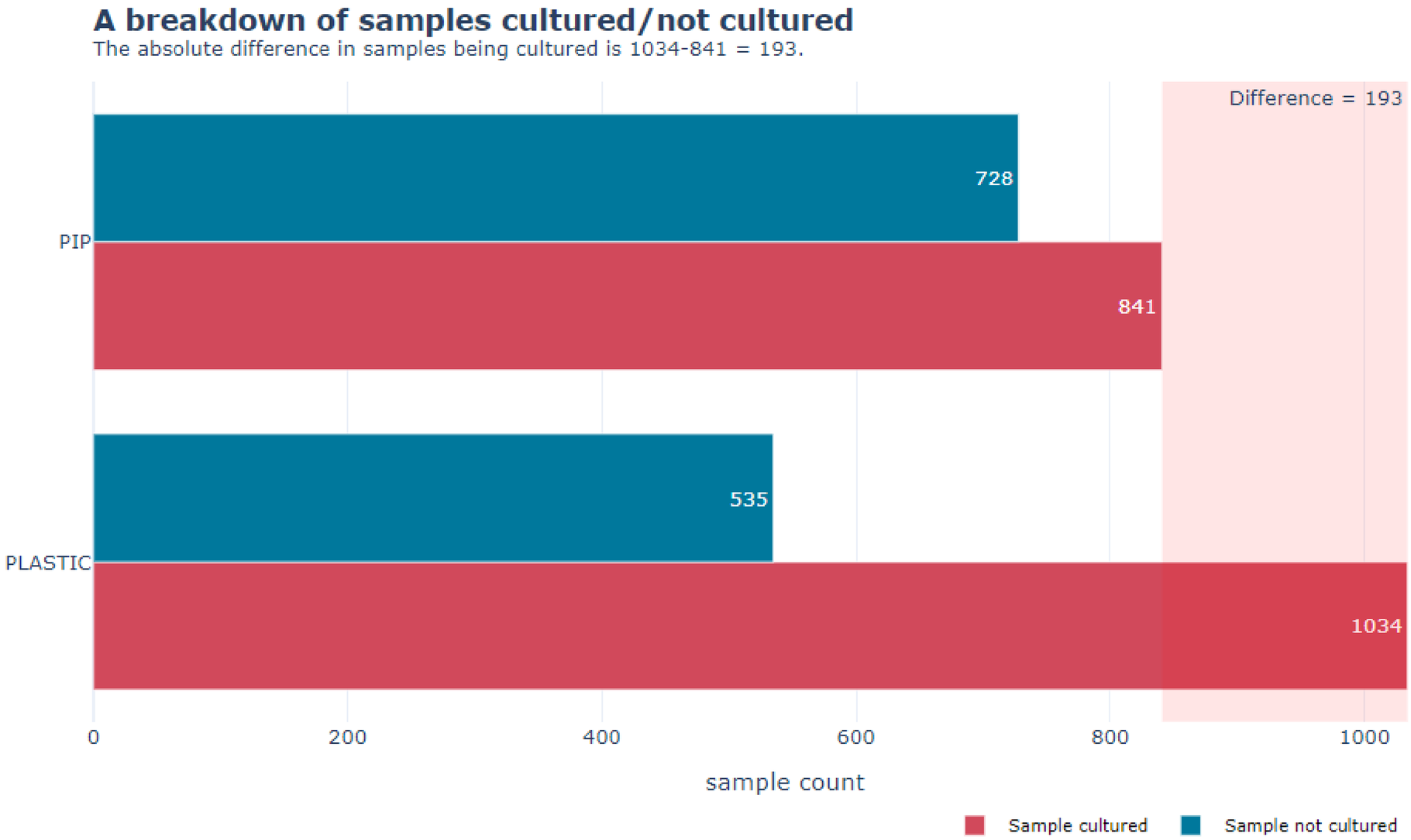
PiP trial

Statistical summary

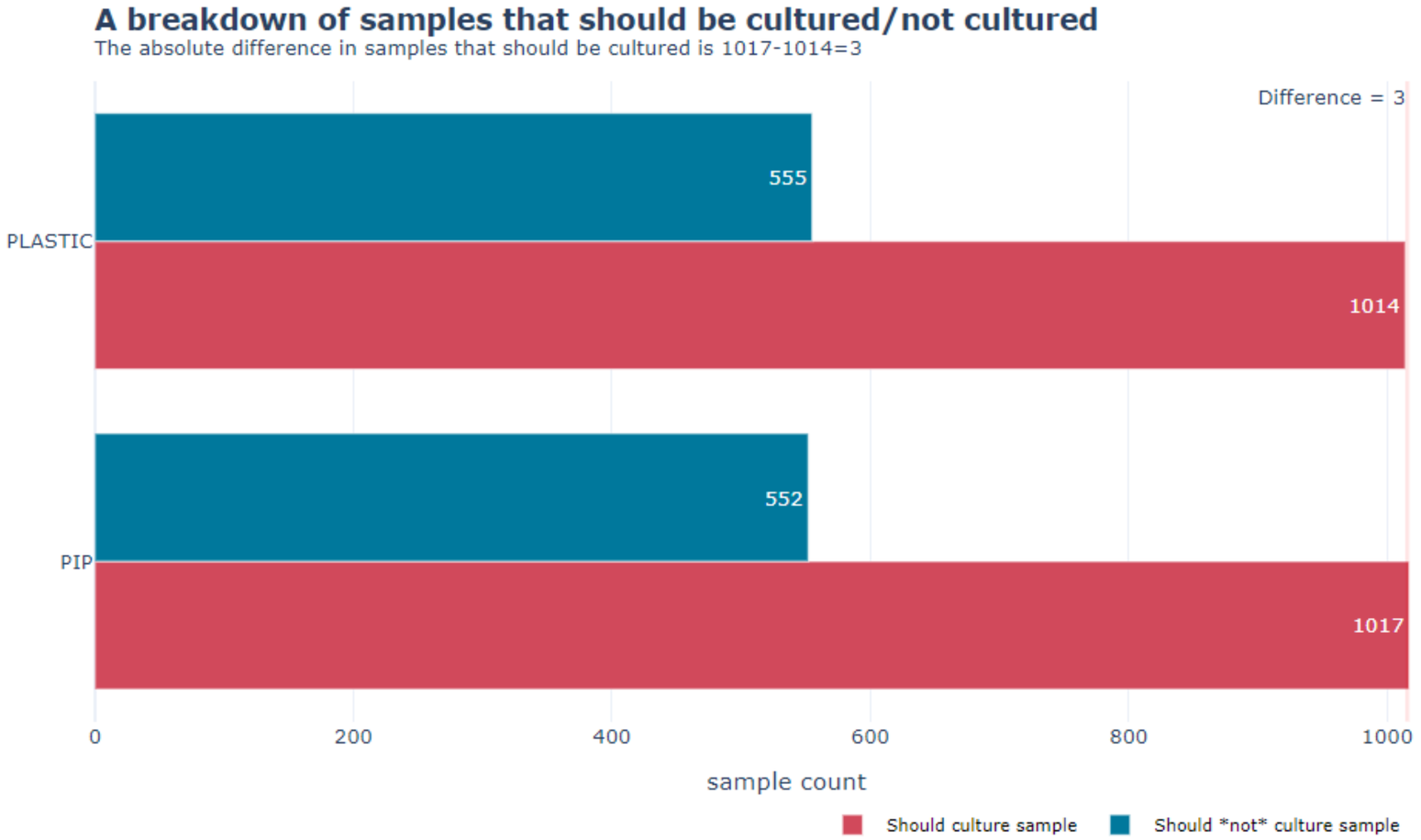
Disparity in number of samples being cultured



Possibly not an issue with PiP

When should a sample be cultured?

- If sample was taken from antenatal, **or**
- sample had WBC count greater than 45, **or**
- sample had all particles count greater than 10,000, **or**
- sample had bacteria count greater than 5.



Agreement between programmable logic & samples actually being cultured

General agreement with the plastic samples

Plastic culture agreement		
	Should culture	Should *not* culture
Did culture	1001	33
Did *not* culture	13	522

Less agreement in PiP samples

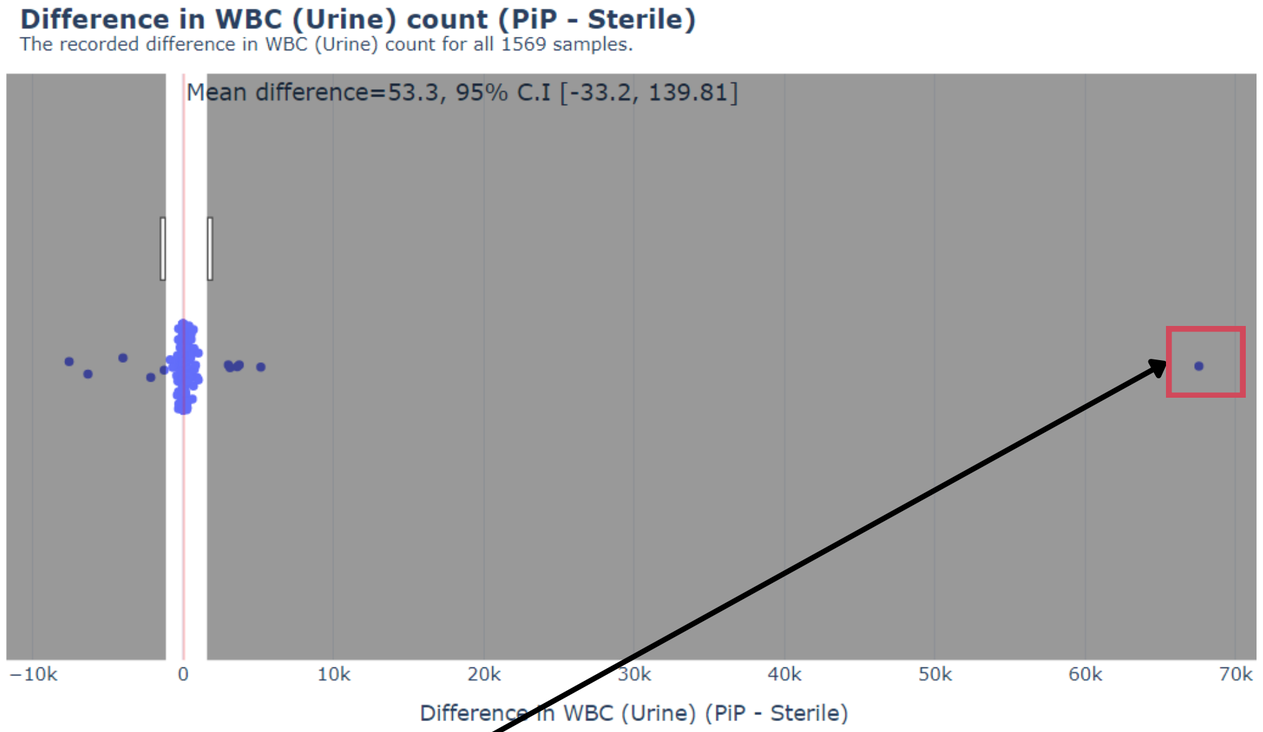
PiP culture agreement		
	Should culture	Should *not* culture
Did culture	821	20
Did *not* culture	**196**	532

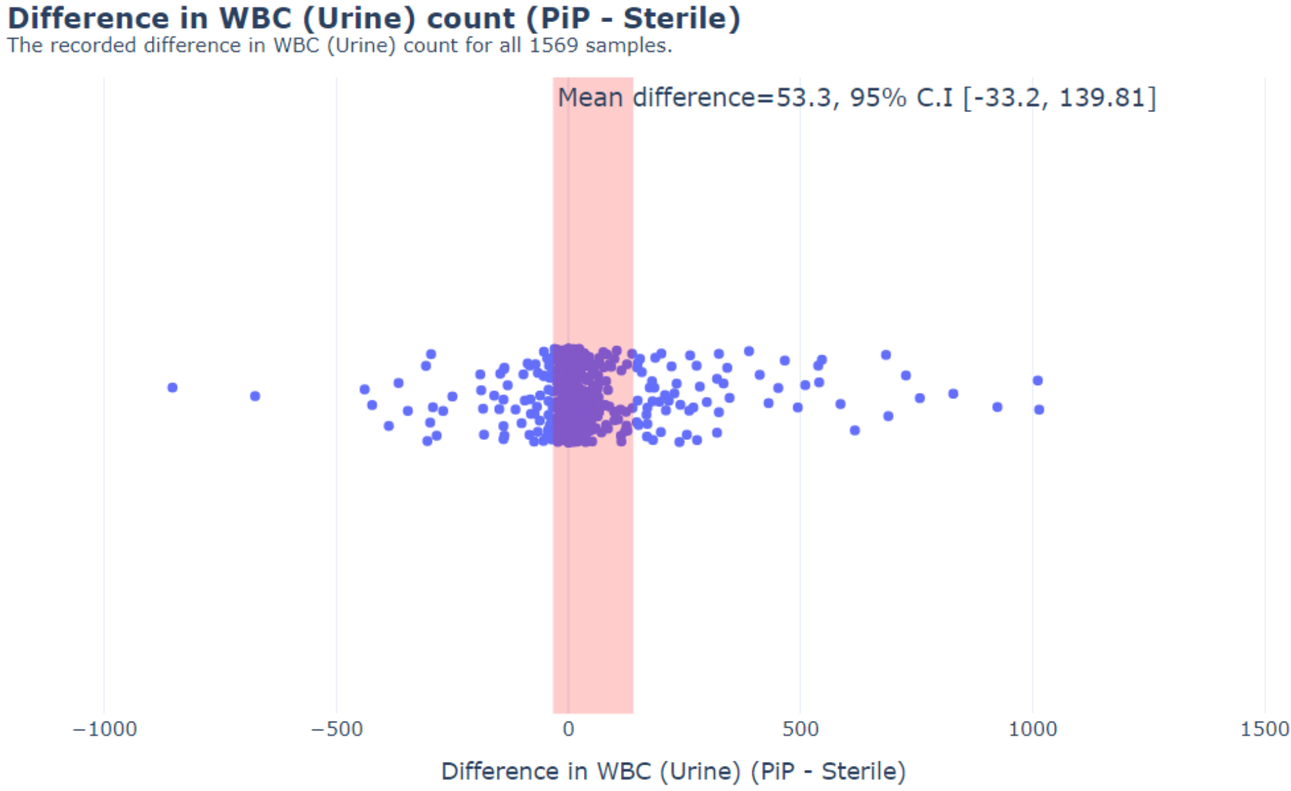
187 of these 196 were paired with samples being taken in the Antenatal ward

Comparison of microscopy results

Its assumed we can ignore potential culture problem for these results

WBC (Urine) count difference

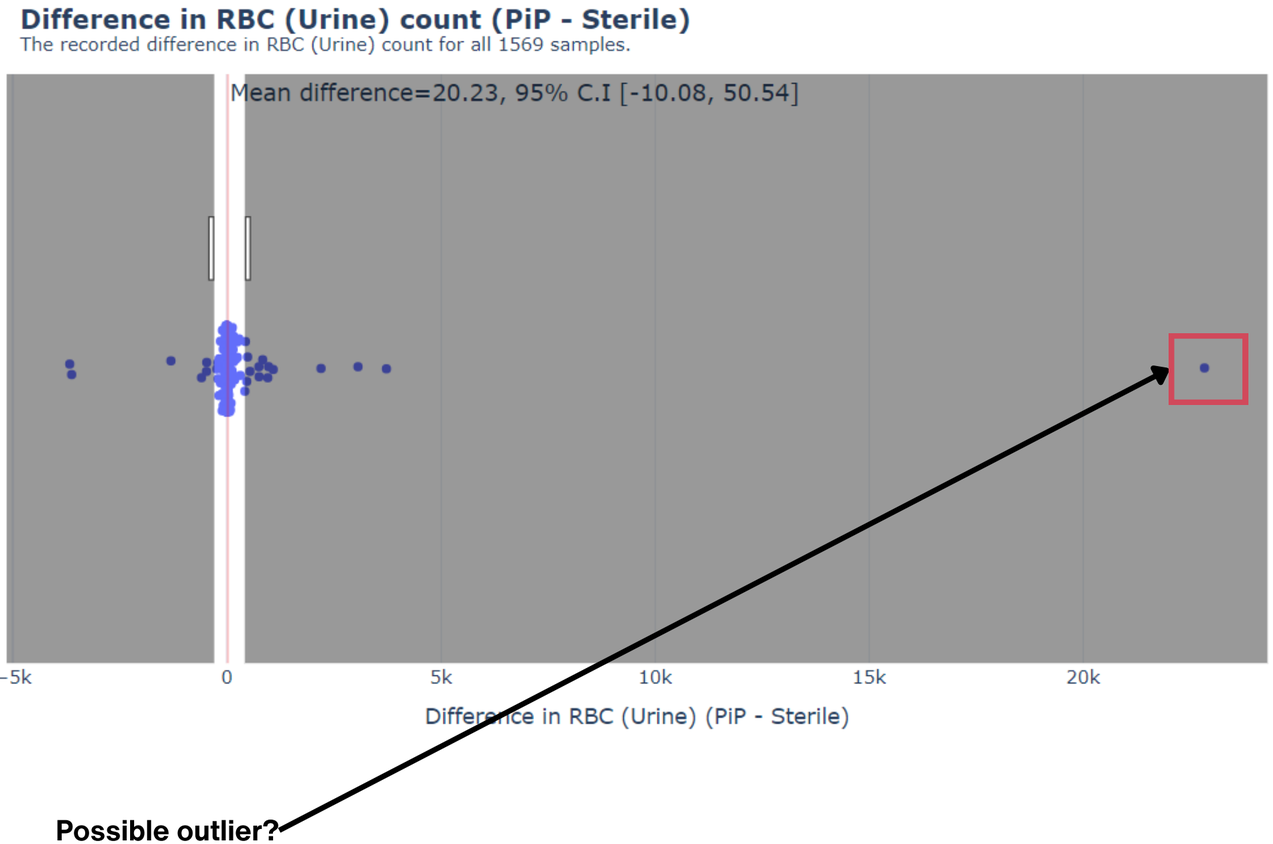




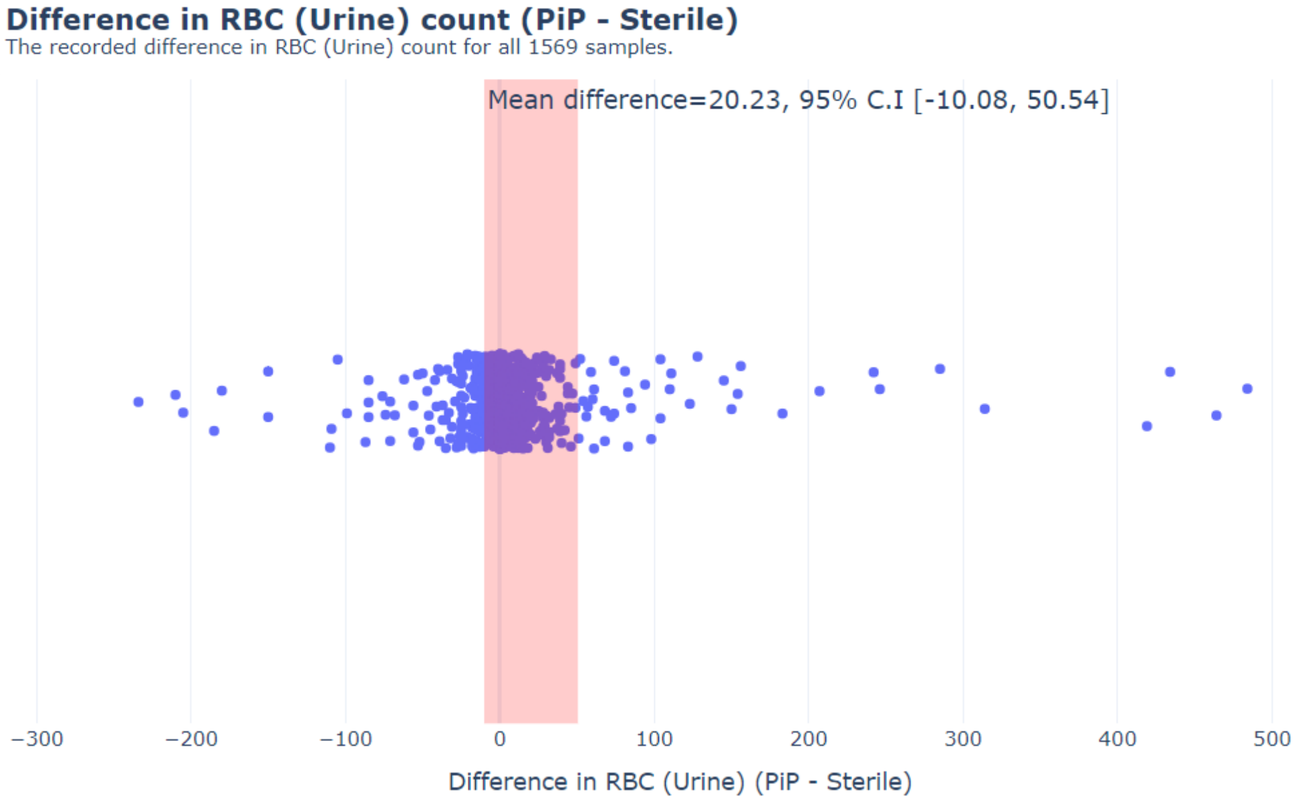
Possible outlier?

Specimen Number	Source Desc	Organism Desc	Growth Desc	All Small Particles	Bacteria	RBC (Urine)	WBC (Urine)
C02366588	PIP TRIAL	Escherichia coli	>100,000/mL	207245.0	0.0	1023.0	72405.0
C02366588	SURGICAL DECISION UNIT TRIAGE	Escherichia coli	>100,000/mL	193605.0	0.0	51.0	4845.0

RBC (Urine) count difference

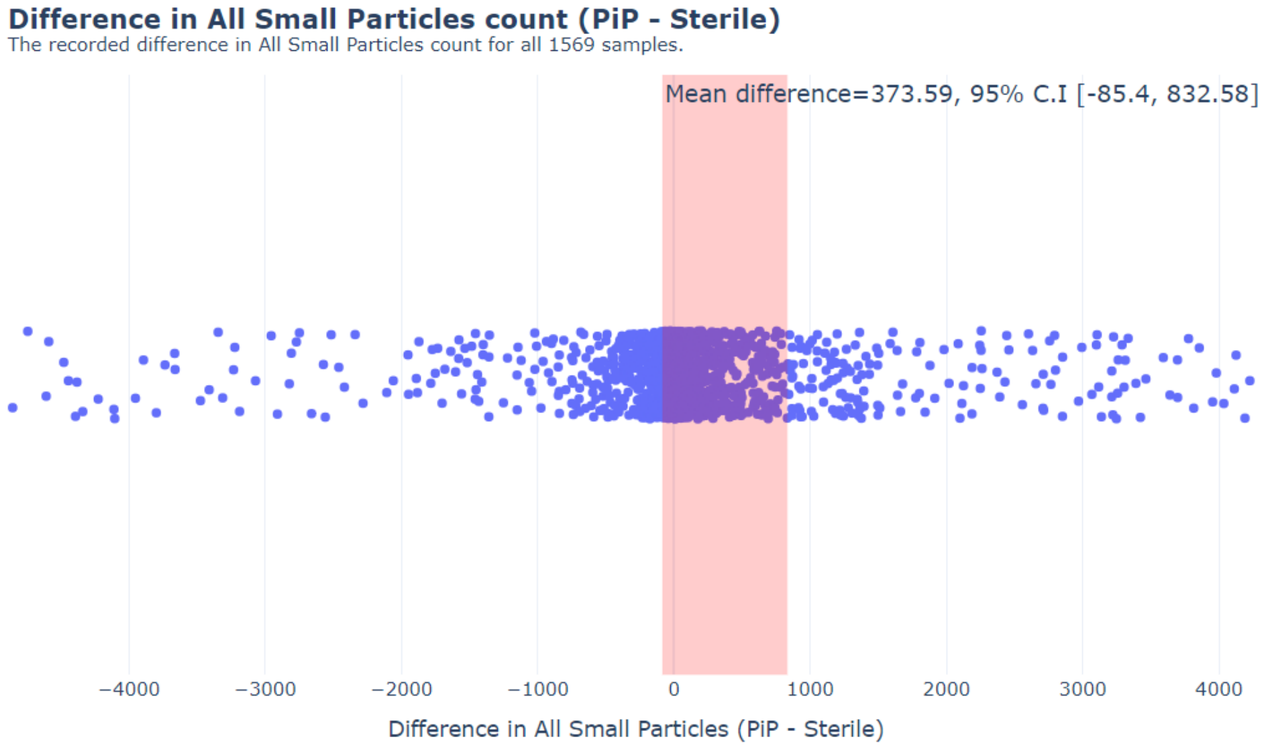


Possible outlier?

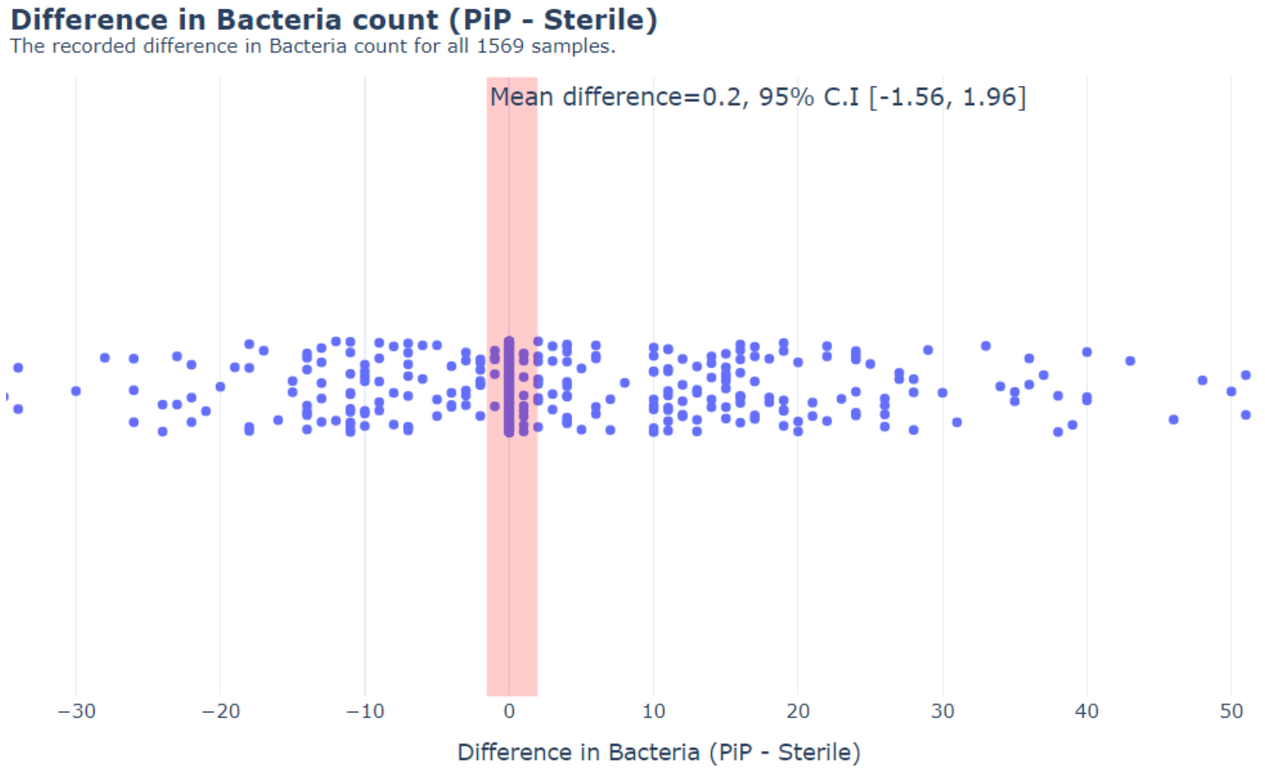


Specimen Number	Source Desc	Organism Desc	Growth Desc	All Small Particles	Bacteria	RBC (Urine)	WBC (Urine)
C02329514	MPH ACCIDENT CENTRE	Enterococcus sp.	>100,000/mL	53218.0	0.0	2787.0	574.0
C02329514	PIP TRIAL	Enterococcus sp.	>100,000/mL	51616.0	0.0	25626.0	4174.0

All Small Particle Count difference



Bacteria Count difference



Microscopy results

WBC, RBC, all small particles & bacteria count difference

Results *keeping* in two possible outliers

variable	mean difference	lower C.I	upper C.I	sample size
WBC (Urine)	53.304598	-33.199412	139.808608	1566
RBC (Urine)	20.231162	-10.082608	50.544932	1566
All Small Particles	373.590793	-85.401876	832.583462	1564
Bacteria	0.201149	-1.560370	1.962668	1566

Results *removing* the two possible outliers

variable	mean difference	lower C.I	upper C.I	sample size
WBC (Urine)	7.874041	-9.584331	25.332413	1564
RBC (Urine)	5.032609	-4.955785	15.021002	1564
All Small Particles	366.362356	-92.909577	825.634289	1562
Bacteria	0.201407	-1.562367	1.965181	1564

- PiP does generally seem to result in a higher count (i.e., mean difference is positive).
- The confidence intervals do always contain zero (i.e., a 0 difference is a possible value for the mean difference)
- The outliers have a large impact on mean difference for WBC/RBC counts, resulting in larger differences/CI's.
- **What is equivalent? Is there a better way to compare? (i.e., comparing samples that went on to be cultured as a result of microscopy etc...)**

Comparison of negative culture results (mixed growth & no significant growth)

203 samples removed (to make comparison fair)

Removed samples- If either the PiP or Plastic ***should*** have been cultured but wasn’t. In these cases, the entire specimen has been removed from the analysis, since it is not fair to say that one has a negative result, given that it should have been cultured.

Negative culture summary

Mixed growth		
	PiP +	PiP -
Plastic +	80	21
Sterile -	15	1250

No significant growth		
	PiP +	PiP -
Plastic +	623	41
Sterile -	42	660

__Equivalence testing__ Quantifying difference in proportion of **Mixed Growth**

plastic proportion = 80 + 21 / (80+21+15+1250)
=101/1366
= 0.073939 (approx. 7.4%)

PiP proportion = 0.069546 (approx. 7%)

Difference in proportion = 0.069546 - 0.073939 = -0.004386 (approx. 0.44%), 95% CI [-0.013215, 0.004443]

__Equivalence testing__ Quantifying difference in proportion of **No significant growth**

plastic proportion = 0.486091

PiP proportion = 0.486823

Difference in proportion = 0.000731,
95% CI [-0.012478, 0.013940]

Negative culture summary table

organism	PiP + prop.	plastic + prop.	difference	lower C.I	upper C.I	ratio
Mixed Growth	0.069546	0.073939	-0.004386	-0.013215	0.004443	0.940594
No significant growth	0.486823	0.486091	0.000731	-0.012478	0.013940	1.001506
Culture Not indicated.	0.388726	0.382138	0.006579	-0.005317	0.018475	1.017241
Streptococcus Group B	0.001275	0.001275	0.0	-0.001764	0.001764	1.0

Step. B for ***non*** antenatal samples

Summary thoughts:

- General agreement between PiP and plastic- not perfect agreement, needs defined thresholds.
- The confidence intervals do always contain zero (i.e., a 0 difference is a possible value for the mean difference)
- Are there any thresholds that would be appropriate to use for equivalence?

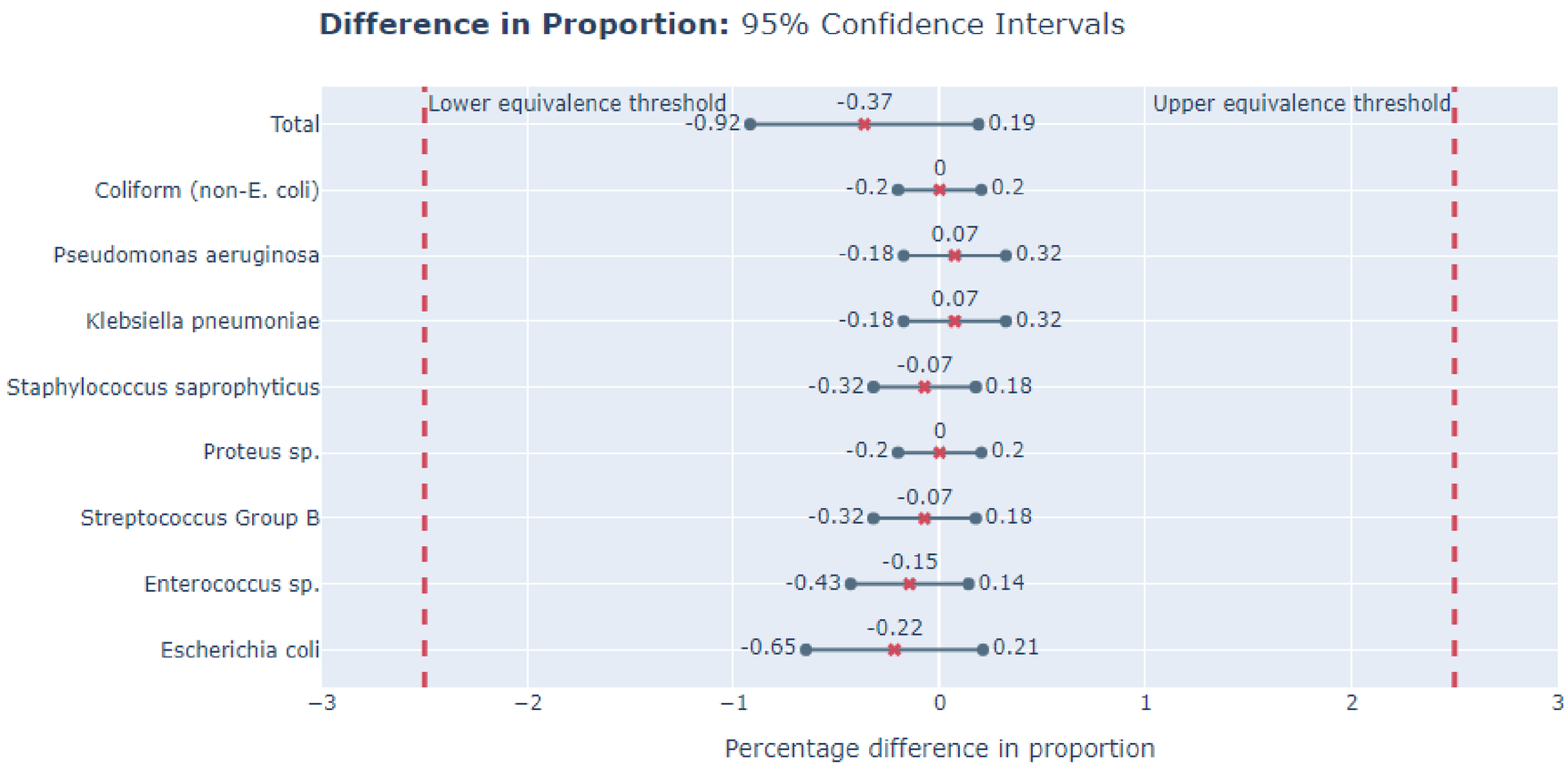
Comparison of positive culture results

203 samples removed (to make comparison fair)

Positive culture results

(Strep .B is only detected for antenatal samples)

Microorganism	Detected in PiP	Detected in Plastic: True	Detected in Plastic: False
Escherichia coli	**True**	44	2
	False	5	1315
Enterococcus sp.	**True**	2	0
	False	2	1362
Streptococcus Group B	**True**	2	0
	False	1	522
Proteus sp.	**True**	4	0
	False	0	1362
Staphylococcus saprophyticus	**True**	4	0
	False	1	1361
Klebsiella pneumoniae	**True**	0	1
	False	0	1365
Pseudomonas aeruginosa	**True**	3	1
	False	0	1362
Coliform (non-E. coli)	**True**	11	0
	False	0	1355
Total	**True**	70	4
	False	9	1283



Summary table for positive cultures

Organism	PiP + proportion	Plastic + proportion	Difference (PiP - Plastic)	Estimated difference per 10, 000 samples	Lower C.I	Upper C.I	Difference ratio
Escherichia coli	0.033675	0.035871	-0.00219	~ 22 missed	-0.00649	0.002104	0.938776
Enterococcus sp.	0.001464	0.002928	-0.00146	~ 14 missed	-0.00433	0.001402	0.5
Streptococcus Group B	0.001464	0.002196	-0.00073	~ 7 missed	-0.00321	0.00175	0.666667
Proteus sp.	0.002928	0.002928	0	0	-0.00203	0.002026	1
Staphylococcus saprophyticus	0.002928	0.00366	-0.00073	~7 missed	-0.00321	0.00175	0.8
Klebsiella pneumoniae	0.000732	0	0.000731	~7 additional	-0.00175	0.003212	N/A
Pseudomonas aeruginosa	0.002928	0.002196	0.000731	~7 additional	-0.00175	0.003212	1.333333
Coliform (non-E. coli)	0.008053	0.008053	0	0	-0.00203	0.002026	1
All	0.054173	0.057833	-0.00365	~ 37 missed	-0.0092	0.001891	0.936709

Summary thoughts:

- Generally, plastic may detected more than PiP **(importance of defining meaningful equivalence threshold).**
- Some organisms may not be fairly evaluated (low positivity rate i.e.,).
- It may be useful to study samples that disagree (13 in total) to see whether there is a common pattern between them