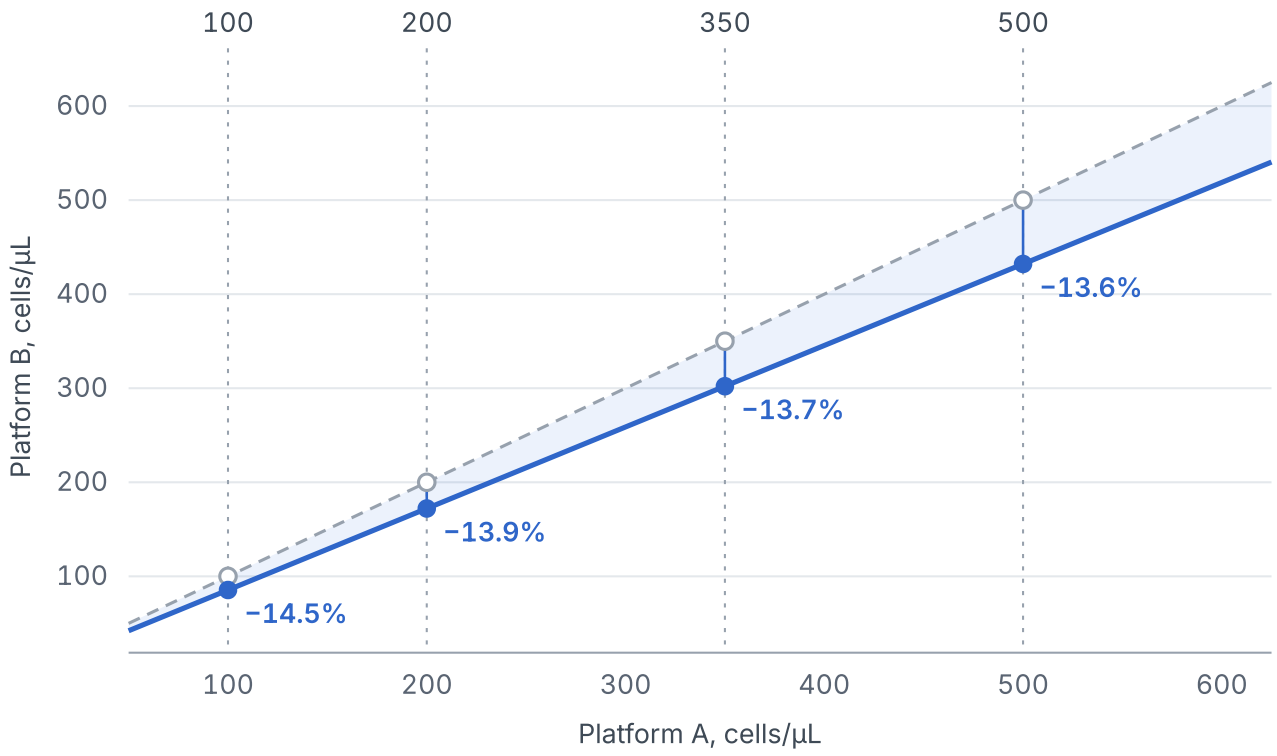
NakedSignal

SAMPLE

LABORATORY REPORT

Analyser change report

CD4 absolute count: platform A to platform B



PREPARED FOR
Sample laboratory

ANALYTE
CD4 absolute count

PAIRED RESULTS
1,885

ISSUED
October 2026

Executive summary

1,885
paired results, measured on both platforms

535
results changed category, against about 238 from repeat testing alone

66%
of the excess caught by flagging results near a threshold for re-test, with the comparison line, on unseen data (line alone: 46%)

15%
of results re-tested to achieve it

Verdict

Platform B shifts CD4 results down by a near-constant share, so the gap in cells grows with the count. Unadjusted, 535 of 1,885 results change category at 100, 200, 350, 500 cells/µL. Flagging the results that land near a threshold for re-test, with the comparison line applied to the rest, catches 66% of the excess while re-testing 15% of results; the comparison line alone catches 46%.

RECOMMENDATION

Proceed with the change as a managed transition.

1. **Correct** each platform B result to the platform A scale with the comparison line (slope 0.87).
2. **Re-test** results that land inside the re-test band, which reaches 5.51% above each threshold and slightly less (5.22%) below it.
3. **Inform** requesting clinicians with the note on page 6 before the first result is reported.
4. **Confirm** the correction on the laboratory's own paired samples before go-live.

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1. What changed

Across 1,885 paired counts, platform B reads about 14% lower. The comparison line has a slope of 0.87, so the gap widens as the count rises.

Figure 1 Platform B against platform A, with the four clinical thresholds marked

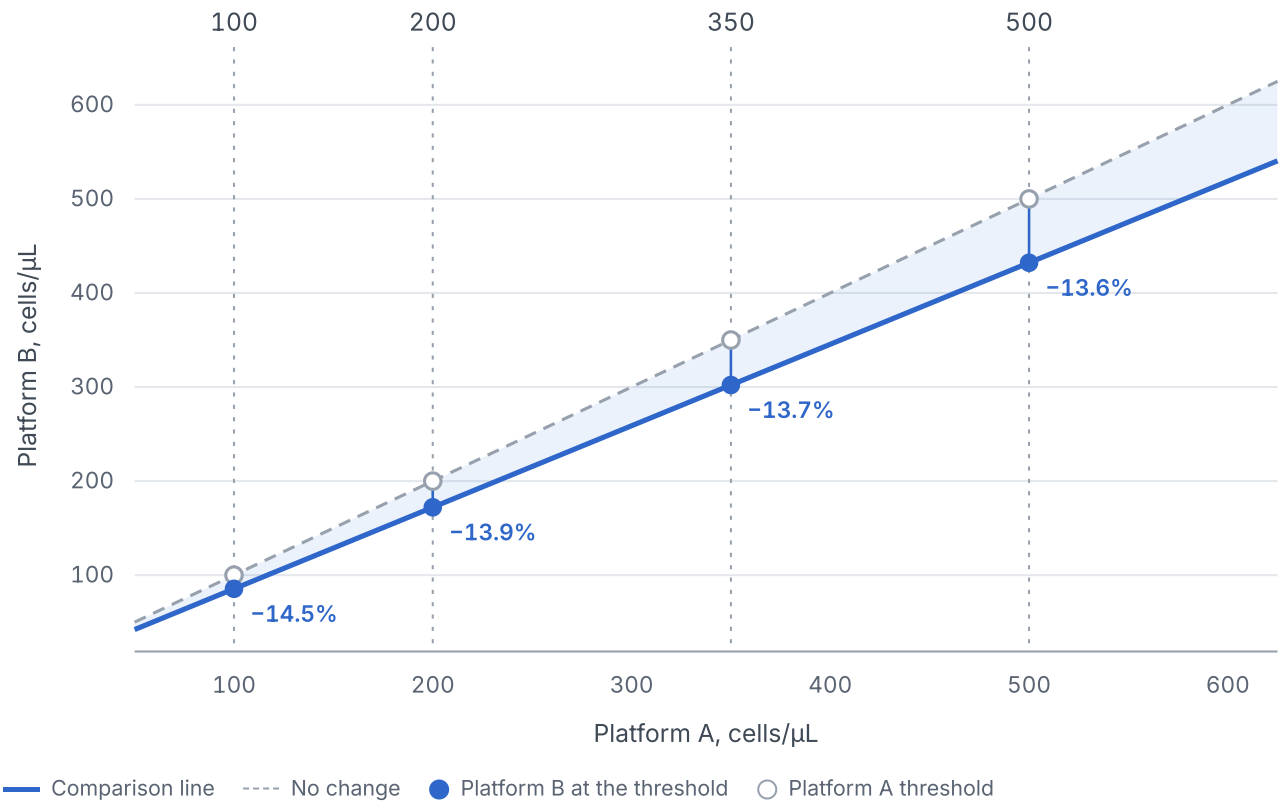
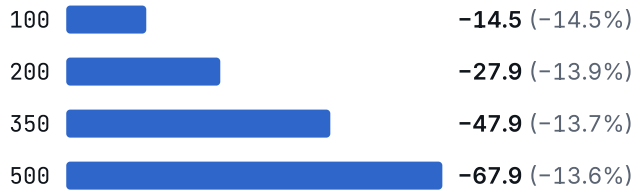


Table 1 Bias at each clinical threshold

Threshold	Platform B reads	Difference	%
100	85.5	-14.5	-14.5
200	172.1	-27.9	-13.9
350	302.1	-47.9	-13.7
500	432.1	-67.9	-13.6

Values in cells/µL, read off the comparison line.

Figure 2 Difference at each threshold



In cells/µL, with the share in brackets. The difference grows with the count while its share stays close to 14%.

2. Results across the clinical thresholds

Repeat testing alone moves some results across a threshold. The question is how many more the change moves.

Figure 3 **Results that changed CD4 category, all four thresholds together**

Changed category between the two platforms, unadjusted

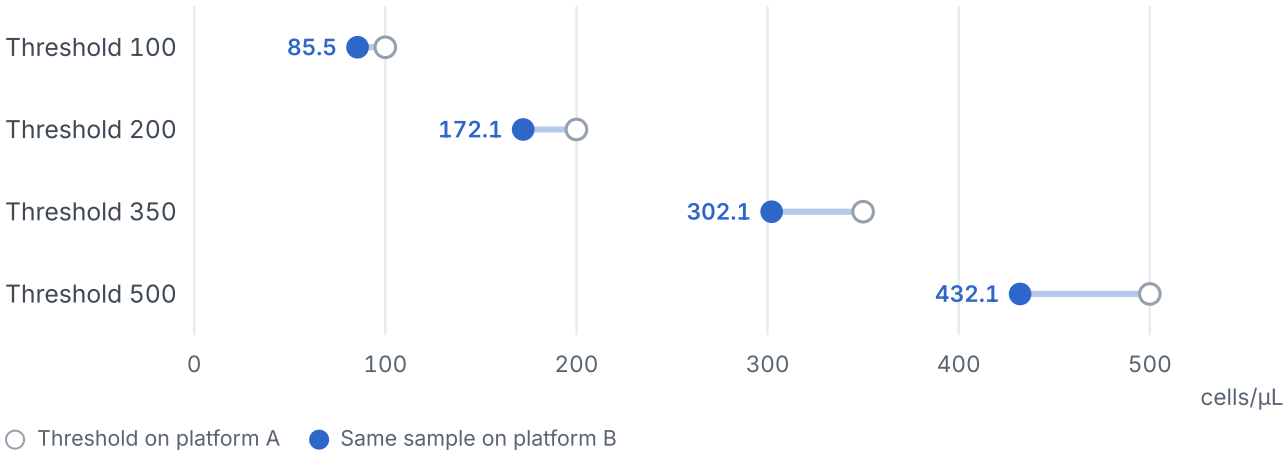
535

Expected from repeat testing alone

about 238 | Excess from the platform change

Reported without adjustment, **535** results fall in a different category on platform B. Repeat testing on one unchanged platform would move about **238** across the same thresholds. The rest is what the change did.

Figure 4 **Where each threshold reads on platform B**



A sample that reads 500 cells/µL on platform A reads about 432.1 on platform B. Results just above a threshold on platform A can therefore fall below it on platform B.

3. Re-test band for the transition

Each platform B result is corrected to the platform A scale. Results that land close enough to a threshold that the change could have moved them are re-tested; the rest are reported.

1
Correct

Apply the comparison line to the new result.

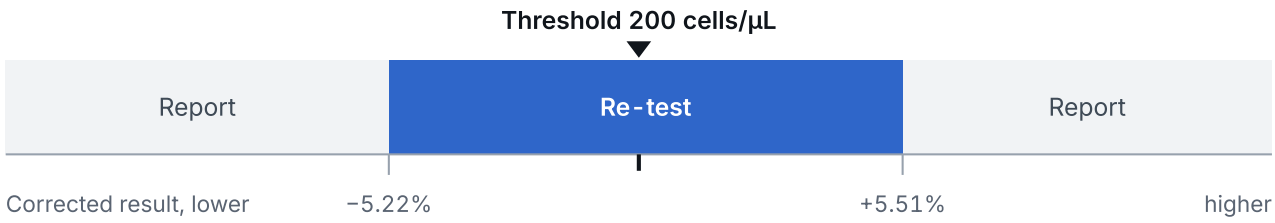
2
Check the band

Is the corrected result within 5.51% above or 5.22% below a threshold?

3
Re-test or report

Inside the band: re-test. Outside: report as usual.

Figure 5 The re-test band around one threshold



The same band applies at each threshold: 100, 200, 350, 500 cells/µL.

How it performed on unseen data

The band was fitted on part of the paired results and measured on results it had not seen.

Figure 6 Share of the excess category changes caught

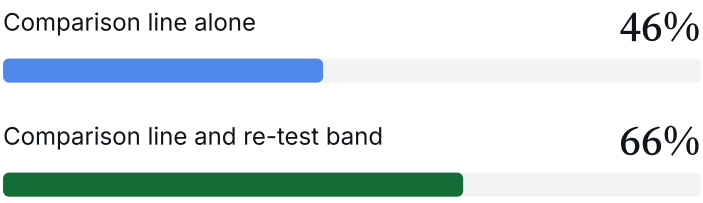
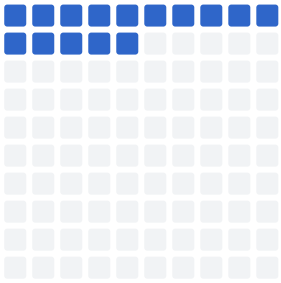


Figure 7 Workload



15%
of results re-tested during the transition

4. Note for requesting clinicians

A standalone page the laboratory can send to requesting clinicians before go-live, adapted to its own words.

FROM

Sample laboratory

TO

Requesting clinicians

SUBJECT

CD4 counts: change of measuring platform

EFFECTIVE FROM

[Go-live date]

CD4 counts are moving to a new measuring platform

The laboratory is moving CD4 absolute counts to a new platform. On the same samples, the new platform reads about 14% lower than the old one, and the gap grows with the count.

What the laboratory is doing

- Results that fall close to a threshold are flagged and re-tested before they are reported.
- Other results are converted to the old scale with the comparison line, which removes most of the average difference between the platforms but not each patient's.
- The thresholds we report against are 100, 200, 350, 500 cells/µL.

What this means for you

- Most patients will see no change in CD4 category.
- If a patient's category differs from an earlier result, the platform change is one possible reason.
- Please contact the laboratory before acting on a change of category alone.

QUESTIONS

Contact the laboratory duty scientist.

5. Method and data

Data

1,885 CD4 absolute counts measured on both platforms, from a published method comparison. Thresholds at 100, 200, 350, 500 cells/µL; those at 350 and 500 cells/µL are former cut-offs for starting treatment, kept because the study's authors categorised CD4 counts at them.

Comparison

Passing-Bablok regression of platform B on platform A gives the comparison line. Bias at each threshold is read off that line.

Category changes

Each pair is placed in a CD4 category on each platform. The count of changes is set against the number expected from repeat-test imprecision on one unchanged platform.

Re-test band

The band is fitted on part of the data and measured on the remainder, so the figures on page 5 describe results the band had not seen.

Table 2 **Key measures**

Paired results	1,885
Comparison line slope	0.867 (95% interval 0.857 to 0.878)
Comparison line intercept (cells/µL)	-1.2
Mean difference, platform B against A	-14.3%
Clinical thresholds (cells/µL)	100, 200, 350, 500
Re-test band around each threshold	5.51% above, 5.22% below
Repeat-test imprecision	Default value, not measured at a site

SOURCE

Coetzee LM, Glencross DK (2017). *PLoS One*. doi:10.1371/journal.pone.0187456; PMC5669480. Licence: CC BY 4.0. Re-analysed by NakedSignal.

Appendix: assumptions and limits

> **Data.** This sample is built from a public, open-access method comparison. A laboratory's report uses its own paired results.

> **Imprecision.** The number expected from repeat testing uses a default repeat-test imprecision. A laboratory's report uses its own measured imprecision.

> **Thresholds.** Results are categorised at the thresholds the study's authors used. A laboratory's report uses the thresholds it reports against.

> **Scope.** Figures describe this dataset. Another laboratory, population or reagent lot can differ.

> **Verification.** The report supports, and does not replace, the laboratory's own verification under its quality system.

NakedSignal

A report built from your own paired results

Bias at each of your decision limits, the patients who cross them, a re-test band tested on unseen data and a clinician note, for every analyte you are changing.

nakedsignal.com/contact