

Sample analyser-change report: CD4

■ SAMPLE

Sample built from public data. This is not a customer report. The pairs are an open-access deposit, run by NakedSignal's program as if a laboratory had exported them. Repeat-test imprecision is assumed. No laboratory commissioned or reviewed it. It shows three of the seven report parts in full and three in part; the other one needs more than one site. The sample page lists each part and what is not shown, with the reason.

What a laboratory receives when one platform replaces another: what changed, which results cross a clinical threshold, and how to manage the switch.

run 25 September 2026 · config 6eb23df45893 · run file sha256 5586cd892ef1

What this sample shows

A laboratory's report has seven parts. This sample is built from one public run file, so it shows some parts in full, some in part, and one not at all. Each is listed with the reason.

Part of the report	In this sample
01 The comparison line, with its interval	Shown. The slope with its interval, and the intercept.
02 Bias, with limits of agreement	In part. The mean difference is shown. The limits of agreement are not, because the run file this site is built from does not carry them.
03 Bias at each of your own decision limits	In part. Shown at each threshold, read off the comparison line. The run file carries no interval at each threshold, so none is shown.

Part of the report	In this sample
04 Patients across each limit, in each direction	In part. One count across all four thresholds together, against repeat testing. The run file this site is built from carries only that combined count, so the count per threshold and per direction is not shown.
05 A re - test band for the transition	Shown. The band width and how it performed on data it was not fitted to.
06 A one - page note for requesting clinicians	Shown. A sample note, written from the same numbers.
07 For networks, whether sites report interchangeably	Not shown. The sample is one site, so there is nothing to compare across sites.

1. What changed

1,885 CD4 counts were measured on both platforms. On average the new platform reads about 14% lower than the old one. The comparison line has a slope of 0.87, so the gap grows with the count.

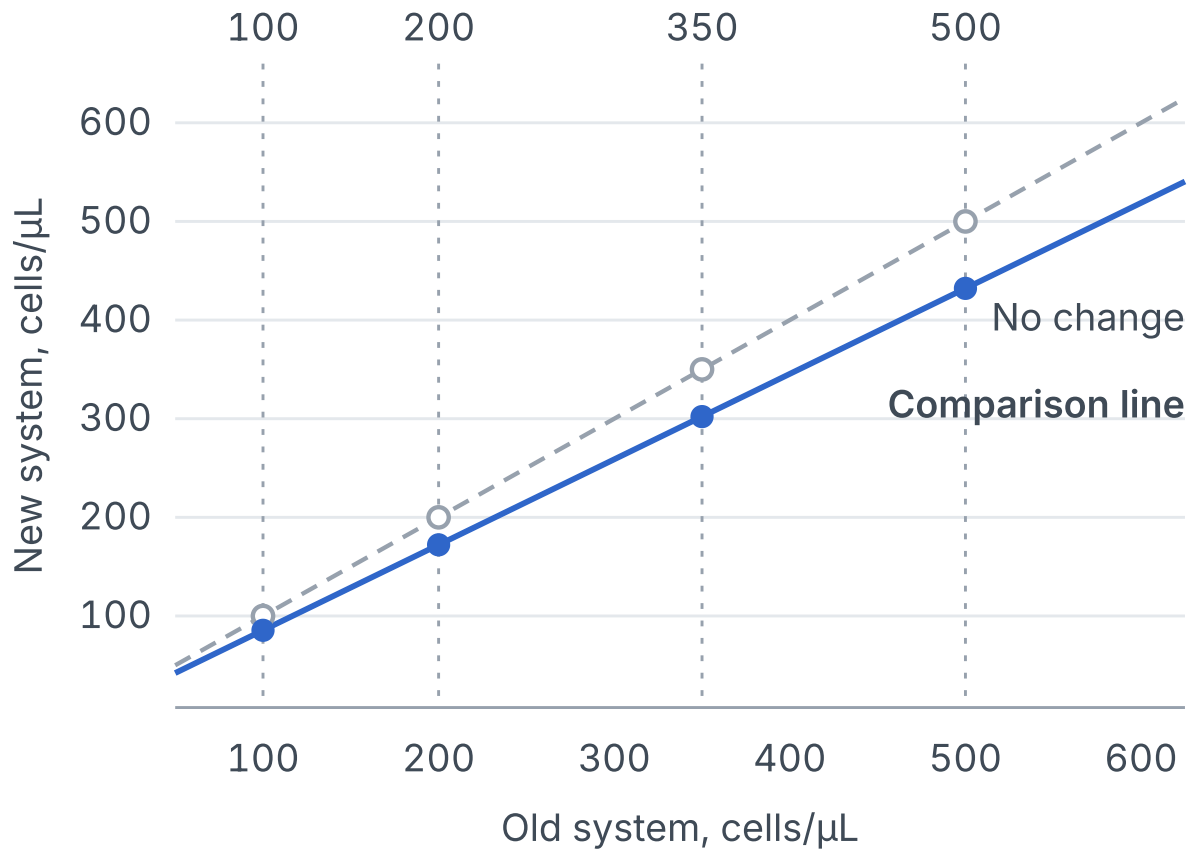


Fig. 1. Where the new platform reads at each CD4 clinical threshold. The comparison line (slope 0.87) sits below the line of no change, so the new platform reads lower, by about 14% on average across the paired counts.

Source Coetzee LM, Glencross DK (2017). *PLoS One*. [doi:10.1371/journal.pone.0187456](https://doi.org/10.1371/journal.pone.0187456); [PMC5669480](https://pubmed.ncbi.nlm.nih.gov/35669480/) (title on the source page; it names the instruments). Licence: [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/).

Changes: Paired results re-analysed by NakedSignal's program; instruments described generically; only derived results are shown. Repeat-test imprecision is assumed. No laboratory commissioned or reviewed it.

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2. Bias at each clinical threshold

Where the new platform reads at each threshold, read off the comparison line. The run file gives the slope's interval but no interval at each threshold, so none is shown here; a laboratory's report gives one.

Threshold (cells/ μ L)	New platform reads (cells/ μ L)	Difference (cells/ μ L)	I
100	85.5	-14.5	
200	172.1	-27.9	
350	302.1	-47.9	
500	432.1	-67.9	

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3. Which results cross a clinical threshold

The clinical thresholds are 100, 200, 350, 500 cells/ μ L. Reported without adjustment, 535 results fall in a different CD4 category on the new platform. Repeat testing on one unchanged platform would move about 238 results across the same thresholds, so the rest is what the change itself did.

This sample counts crossings across all four thresholds together. A laboratory's report also gives the count at each threshold and in each direction (old category to new category); the run file this page is built from carries only the combined count, so that table is not shown here.

All four clinical thresholds (100, 200, 350, 500 cells/ μ L)

Crossed after the change: **535**



Expected from repeat testing alone: **about 238**



Fig. 2. Sample built from public data: 1,885 paired CD4 counts from an open-access deposit, one platform replaced by another. Reported without adjustment, 535 results change category against about 238 expected from repeat testing alone. Correcting with the comparison line and re-testing inside the band removes 66% of that excess on data the band was not fitted to, while re-testing 15% of results.

Source Coetzee LM, Glencross DK (2017). *PLoS One*. [doi:10.1371/journal.pone.0187456](https://doi.org/10.1371/journal.pone.0187456); [PMC5669480](https://pubmed.ncbi.nlm.nih.gov/35669480/) (title on the source page; it names the instruments). Licence: [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/). Changes: Paired results re-analysed by NakedSignal's program; instruments described generically; only derived results are shown. Repeat-test imprecision is assumed. No laboratory commissioned or reviewed it.

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4. Review band during the transition

Each new result is corrected to the old scale with the comparison line. Results that land inside a narrow band around a threshold are close enough that the change could have moved them; they are candidates for review, and the laboratory decides whether to repeat them. For this deposit the band is 5.51% either side of each threshold.

Tested on data the band was not fitted to, the comparison line and band together catch 66% of the excess crossings while re-testing 15% of results. The comparison line alone catches 46%.

5. A note for requesting clinicians

A sample of the one-page note, written from the same numbers. A laboratory writes its own, in its own words.

■ **SAMPLE** CD4 counts: change of measuring platform

The laboratory is moving CD4 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.

Without adjustment, some results near the thresholds we report against (100, 200, 350, 500 cells/ μ L) would fall in a different category than on the old platform. During the transition the laboratory corrects new results to the old scale and reviews results that fall close to a threshold, so the category you see keeps its meaning.

If a patient's CD4 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.

6. Limits

- These are public research data, not a laboratory's own. A laboratory's report is built from its own paired results and its own thresholds.
- Repeat-test imprecision is assumed, not measured at this site. With a laboratory's own imprecision the expected count changes.
- Crossings are counted across all four thresholds together.
- The thresholds at 350 and 500 cells/ μ L are former cut-offs for starting treatment. They are kept because the deposit's authors categorised CD4 counts at them, as guideline cut-offs at the time the data were collected.

- For networks, the report compares sites with each other. The sample is one site, so that part is not shown.
- The report supports a laboratory's verification work. It is not an ISO 15189 verification, not a regulatory clearance and not advice about an individual patient.
- The platforms are described generically; the deposit names them.

Source Coetzee LM, Glencross DK (2017). *PLoS One*. [doi:10.1371/journal.pone.0187456](https://doi.org/10.1371/journal.pone.0187456); [PMC5669480](https://pubmed.ncbi.nlm.nih.gov/35669480/) (title on the source page; it names the instruments). Licence: [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/).
Changes: Paired results re-analysed by NakedSignal's program; instruments described generically; only derived results are shown.

What the laboratory also receives, on its own computer only

The list of the samples that changed category, by the laboratory's own sample reference, so each one can be reviewed. It stays on the laboratory's computer and is never shown here or sent to us. Counts from one to four are shown as "<5" in anything that leaves.

Changing a platform soon?