



WHITE PAPER
CMV Detection in CSF and EDTA Plasma

Comparison Study

Fast. Reliable. Sensitive.

Feasibility Study Evaluation of the ANCHOR CMV PCR Kit
with the MagNA Pure 96 and cobas z480 Systems

EXECUTIVE SUMMARY

Cytomegalovirus (CMV) poses a significant risk in immunocompromised patients, requiring precise and timely diagnostics.

While the ANCHOR CMV PCR Kit is CE-certified for use with different workflow components this white paper presents a comparative study evaluating its analytical performance, sensitivity, and precision specifically when used in combination with the MagNA Pure 96 nucleic acid extraction platform and the cobas z480 PCR cyclers.

The study results confirm consistent performance across two independent laboratories, with 300 IU/ml detected in 100% of both sample types and 100 IU/ml detected in ~92% (CSF) and 79% (plasma). The kit also showed high reproducibility across a broad range of viral load concentrations and excellent agreement with its declared analytical sensitivity.

These findings underscore the robustness and reliability of the ANCHOR CMV PCR Kit, confirming its suitability for high-confidence CMV detection in clinical workflows.

1. STUDY OBJECTIVE

The primary objective of this study was to assess the compatibility and analytical performance of the ANCHOR CMV PCR Kit in combination with the MagNA Pure 96 nucleic acid extraction system and the cobas z480 PCR cycler (both Roche). The study focused on two clinically relevant sample

types: EDTA-plasma and cerebrospinal fluid (CSF).
Specifically, the study evaluated the sensitivity of the assay, estimated by the lowest viral load detected with a 100% hit rate, and the precision of the system, measured by the reproducibility of results across replicates and between laboratories.

*Disclaimer: The ANCHOR CMV PCR Kit is CE-IVD certified for use with EDTA-plasma. In this study, CSF samples and the applied workflow were used for feasibility purposes only and fall outside the approved intended use.

2. MATERIALS AND METHODS

To conduct the investigation, two identical sample panels were created – one using EDTA-plasma and the other using CSF. Each panel consisted of seven CMV-positive samples at defined concentrations and one CMV-negative sample. All samples were spiked with the 1st WHO International Standard for CMV (NIBSC 09/162).

Nucleic acid extraction was performed using the MagNA Pure 96 system, following the Pathogen Universal 200

Protocol with an input volume of 200 µL and an elution volume of 100 µL. PCR analysis was then conducted using the ANCHOR CMV PCR Kit on the cobas z480 PCR system. Two testing sites participated in this evaluation:

- Labor 28 MVZ GmbH
- ANCHOR Diagnostics GmbH, Hamburg

Both sites followed the same protocols to ensure comparability of results.

3. RESULTS BY SAMPLE MATERIAL

3.1 Cerebrospinal Fluid (CSF)

Sensitivity

The CSF testing demonstrated high sensitivity across both laboratories. All replicates tested positive at concentrations from 5,000 IU/mL down to 300 IU/mL. A slight drop in de-

tection was observed at 200 IU/mL and 100 IU/mL, where 11 out of 12 replicates were positive.

CMV Concentration (IU/mL)	Labor 28	ANCHOR
5,000	6/6	6/6
1,000	6/6	6/6
500	12/12	12/12
400	12/12	12/12
300	12/12	12/12
200	11/12	11/12
100	11/12	11/12

These findings indicate a detection limit of 300 IU/mL which, which aligns with the analytical sensitivity of 0.6 IU/µL as stated in the kit's Instructions for Use (IFU).

Precision

Precision was assessed by evaluating the coefficient of variation (%CV) across a range of viral concentrations. For CSF

samples, the %CV was calculated separately for each laboratory.

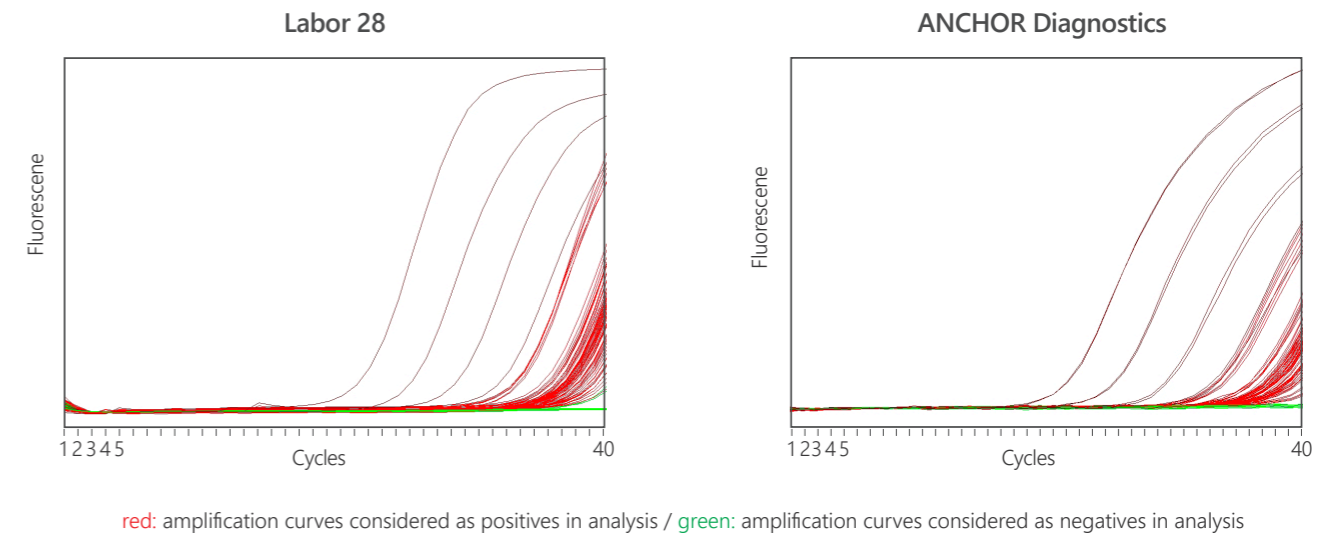
CMV Concentration	Labor 28 CV%*	ANCHOR CV%*
5000 IU/mL	24.3	34.2
1000–300 IU/mL	24.0 – 37.6	25.0 – 36.0
200–100 IU/mL	37.2 – 54.5	37.9 – 55.9

*CV% was calculated using IU/µL values

The results confirm high reproducibility across both laboratories at higher and mid-range concentrations. As expected, slightly

elevated variability was observed at the lowest concentration levels, which remains well acceptable for clinical diagnostics.

Amplification curves for sensitivity and precision testing using CSF



3.2 EDTA-Plasma

Sensitivity

The plasma testing results showed strong agreement between the two laboratories at higher concentrations. Minor

drops in detection were observed at lower concentrations, particularly at 200 IU/mL and 100 IU/mL in one of the labs.

CMV Concentration (IU/mL)	Labor 28	ANCHOR
5,000	6/6	6/6
1,000	6/6	6/6
500	12/12	12/12
400	12/12	12/12
300	12/12	12/12
200	12/12	9/12
100	11/12	8/12

These results suggest a detection limit of 300 IU/mL, reaffirming the assay's strong analytical sensitivity of 0.6 IU/µL as stated in kit's Instructions for Use (IFU).

Precision

For EDTA-plasma samples, %CV values were again evaluated separately per site and are shown below:

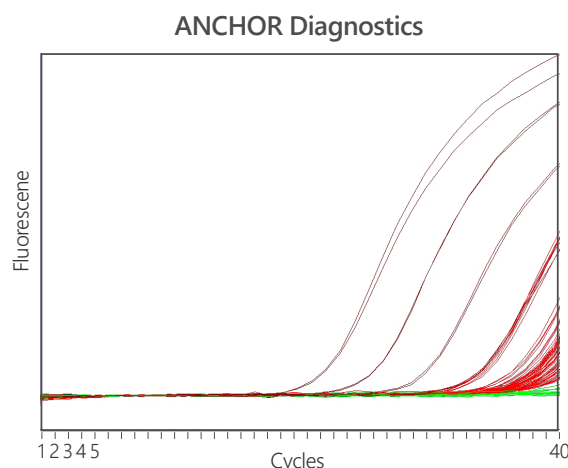
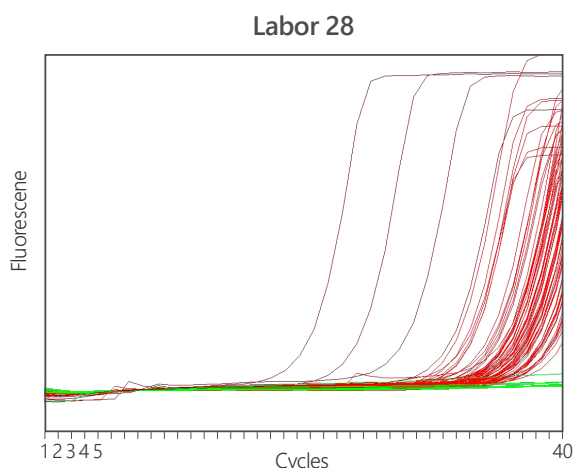
CMV Concentration	Labor 28 CV%*	ANCHOR CV%*
5000 IU/mL	32.6	28.3
1000–300 IU/mL	50.3 – 55.0	26.7 – 59.3
200–100 IU/mL	41.1 – 44.9	21.6 – 39.3

*CV% was calculated using IU/ μ L values

Both labs reported consistent results with low %CVs at higher concentrations. As expected, variability increased at the lower end of

detection. Nonetheless, the average %CV across concentrations represent strong reproducibility and reliable assay performance.

Amplification curves for sensitivity and precision testing using EDTA plasma



red: amplification curves considered as positives in analysis / green: amplification curves considered as negatives in analysis

4. CONCLUSION

The study confirms that the ANCHOR CMV PCR Kit, used with the MagNA Pure 96 extraction system and cobas z480 PCR cyler, provides:

- High sensitivity in both CSF and EDTA plasma samples, consistent with the kit's specifications
- Reliable and reproducible results across different laboratories

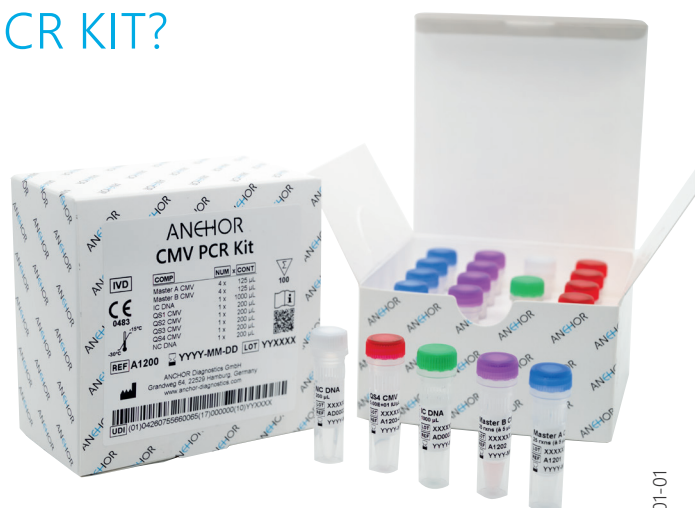
- Strong performance across a range of clinically relevant viral loads

The inclusion of data from two independent laboratories strengthens the robustness of these findings. While CSF testing is outside the current CE-IVD scope, the results indicate the potential for future claim extensions.

5. WHY CHOOSE ANCHOR CMV PCR KIT?

The ANCHOR CMV PCR Kit combines speed, precision, and flexibility making it highly suitable for routine diagnostics. It is especially valuable in time-critical scenarios where it significantly enhances workflow adaptability.

Feature	Benefit
30-minute PCR run time	Fast turnaround, ideal for urgent diagnostics
Compatible with leading PCR platforms	No need for specialized equipment
Flexible and scalable workflow	Fits into existing lab processes
Top analytical performance	Highly reliable results



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