



Afinion™ ACR External Quality Control Log

There are two options for complying with CLIA’s daily QC requirements for non-waived test systems under Section 493.1256 of the regulations:

- Run two levels of external controls daily before patient testing OR
- Laboratories may develop and implement an IQCP for each non-waived test system.

Abbott IQCP Support Documents may be found at <https://www.alere.com/IQCP> The following listed conditions are also required as a minimum requirement:

Afinion™ ACR Controls are recommended for routine quality control testing and should be analyzed:

- With each new shipment of -Afinion™ ACR test kits
- With each new lot of Afinion™ ACR test kits
- At least every 30 days
- When training new operators in correct use of the Afinion™ ACR and the Afinion™ Analyzer
- Anytime an unexpected test result is obtained
- If local, state and/or federal regulations require more frequent testing of control materials

Afinion™ Serial #: _____

AFINION™ ACR EXTERNAL CONTROL ACCEPTABLE RANGES

	CONTROL C I	CONTROL C II
LOT #		
OPEN VIAL/EXPIRATION DATE		
ALBUMIN (mg/L)		
CREATININE (mg/dL)		

DATE	TEST CARTRIDGE LOT#	TEST CARTRIDGE EXPIRATION DATE	CONTROL	ACR RESULT (mg/g)	ALBUMIN RESULT (mg/L)	CREATININE RESULT (mg/dL)	PASS/ FAIL	INITIALS

REVIEWED BY: _____

DATE: _____

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