What is IQCP?

"IQCP" stands for "**Individualized Quality Control Plan**." As of Jan 1, 2016, CMS said **for non-waived tests, either run your external QC daily or implement IQCP**. The non-waived POCT tests affected are GEM4000 tests, ROTEM delta tests, GEM OPL, and ACT. We chose to do IQCP on our non-waived POCT tests.

Why is the advantage of an IQCP over daily QC? QC is run much less frequently (less time and less cost), but actions are taken to mitigate identified risks to ensure patient safety.

What are the 3 key elements of the IQCP?

1. Risk Assessment	2. Quality Control Plan	3. Quality Assessment
Identify **what can go wrong, how bad and how often,** in all three phases (pre-analytical, analytical, and post-analytical) of the testing process. **Think "STREP":** **S** – Specimen: correct collection tube, collecting collection site, adequate mixing of the specimen **T** – Test: follow the procedure, running CVP1 instead of CVP2 or High LQC instead of Low LQC, QC failures, errors, instrument failures **R** – Reagents: degrading reagents, preparing of reagents **E** – Environment: room temp, fridge temp, humidity **P** – Personnel: training and competency, user verifies that a test order in place prior to testing **Now, is there a need for action** (mitigation steps) to reduce the risk for acceptable patient safety**?**	Refers to **external QC testing** on the instrument. For example, we run CVP1, CVP2, CVP3 and CVP4 with every cartridge change on the GEM4000 and High and Low LQC on the Hemochron Signature Elite.	Monitors the ongoing effectiveness based on the risks identified. Review and evaluate at least monthly: • Errors • QC failures • Unusual occurrences • corrective actions • complaints from providers instrument and equipment maintenance and function checks **Are there new risks?** **Did those mitigation steps work for those risks identified last time?** **Go back to #1 Risk Assessment and revise IQCP as needed.**

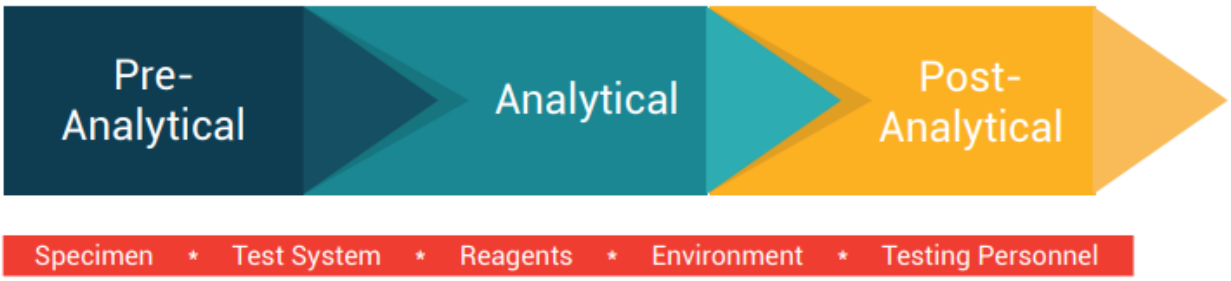
If an inspector asks about the IQCP risks and quality assessment tool for your area, refer him/her to your department super-user and/or Point of Care team.

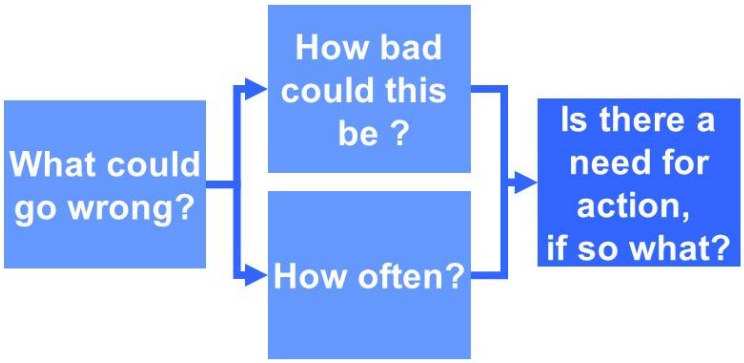
What part do you play in the QC Plan? **I make sure that all quality controls pass prior to patient testing.**

	GEM4000	**HEMOCHRON SIGNATURE ELITE**	**GEM OPL**	**ROTEM**
I do…	• Daily temperature checks (room and fridge) • With every cartridge change: Run external liquid controls (CVP1, CVP2, etc) • Annually: Competency assessments • Monthly: Method comparison ("PCOM") samples are run to compare to the lab's results. • Problems: Call Tech Support and notify the Super User/POCT. • NOTE: The system runs internal controls daily in the background.	• Daily: Check Electronic QC (EQC) and temperature (fridge and room) • Monthly and new lot of cuvettes: external liquid QC (LQC; normal and abnormal) • Annually: Competency assessments and Proficiency Testing • Problems: Call Tech Support and notify the Super User/POCT. • NOTE: EQC is run every 8 hours along with analyzer temp checks	• Daily: Optical QC filter tests (yellow and orange filters) • Weekly and new lots of cuvettes: external liquid controls (LQC; Multi-4 co-ox controls levels 1, 2 and 3). • Annually: Competency assessments • Problems: Call Tech Support and notify the Super User/POCT.	• Daily: Internal QC evaluated, preventive maintenance, and temperature checks (fridge and room) • Weekly and new lots: external liquid controls (LQC; RoTrol N and RoTrol P) and weekly preventive maintenance • Quarterly: preventive maintenance • Semi-annually: Proficiency Testing and preventive maintenance (also every 250 measurements) • Annually: Competency assessments and preventive maintenance • Triennially: preventive maintenance • Problems: Call Tech Support and notify the Super User/POCT.
POCT does…	• Method comparison and linearity studies semi-annually • Monitor temperatures (fridge and room) and humidity • Monthly review of QA and maintenance	• Method comparison study semi-annually • Monitor temperatures (fridge and room) • Monthly review of monthly attestations and maintenance • Departmental Super Users: Submit monthly attestations	• Method comparison and linearity studies semi-annually • Monitor temperatures (fridge and room) • Departmental Super User: Submits monthly attestations	• Monitor temperatures (fridge and room) and humidity • Departmental Super User: Submits monthly attestations

3 ELEMENTS OF AN IQCP:

RISK ASSESSMENT: What can go wrong? How badly (severity)? How often (frequency)? Is the risk acceptable for patient safety? If not, what actions (mitigation steps) need to be taken?





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