Study Guide — BI Problem 3: Medical Innovation (Mid-Unit Test)

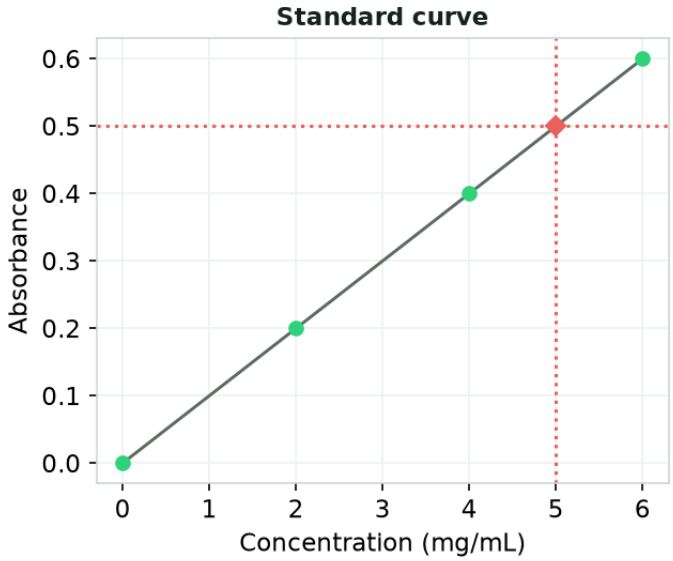
Biomedical Innovations · Problem 3 — Medical Innovation · Modeled on the PLTW Guided Review format

Vocabulary to know cold

Term	Definition
Criteria	The measurable requirements a successful design must meet (e.g., weight under 300 g).
Constraints	Limits placed on a design, such as cost, size, or available materials.
Iterative design	Repeating the build-test-analyze-refine loop to improve a prototype.
Standard curve	A graph of signal vs. known concentration used to read the concentration of unknowns.
Calibration	Setting an instrument's readings against known standards so measurements are accurate.
Accuracy	Closeness of a measurement to the true value.
Precision (reliability)	Consistency of repeated measurements of the same sample.
Negative control	A sample known to lack the target; it should read negative and flags contamination if it does not.
Pre-analytical error	A mistake made before testing — mislabeling, wrong temperature, hemolysis — that ruins results.
Biohazard waste	Material contaminated with potentially infectious agents, disposed of in marked biohazard containers.
Sharps	Needles, blades, and broken glass that must go in a rigid puncture-resistant container.
SDS (Safety Data Sheet)	A document describing a chemical's hazards and safe handling, storage, and disposal.
Centrifuge balance	Loading tubes symmetrically so the rotor does not vibrate, break tubes, or release aerosols.

Worked examples (follow the reasoning)

Example 1. A colorimeter is calibrated with standards giving absorbance 0.20 at 2 mg/mL, 0.40 at 4 mg/mL, and 0.60 at 6 mg/mL. An unknown reads 0.50. Find its concentration.



- Find the slope: absorbance rises 0.20 for every 2 mg/mL, so 0.10 absorbance per 1 mg/mL.
- The line passes through the origin (0,0), so concentration = absorbance / 0.10.
- For the unknown: 0.50 / 0.10 = 5 mg/mL.
- Check: 5 mg/mL sits halfway between the 4 mg/mL (0.40) and 6 mg/mL (0.60) standards — consistent with 0.50.

Answer: The unknown is 5 mg/mL.

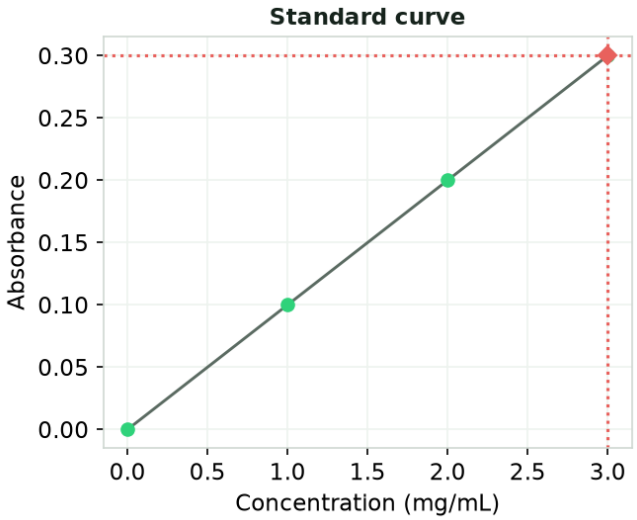
Example 2. A device validation run reports: negative control = POSITIVE signal. What does this mean and what should the team do?

- A negative control contains no target, so it should read NEGATIVE.
- A positive reading on the negative control signals contamination or a false-positive problem.
- Therefore the patient results from that run cannot be trusted.
- The team should discard the run, find and remove the contamination source, and re-test with fresh controls.

Answer: The run is invalid due to likely contamination; discard results, fix the cause, and repeat with controls.

Practice questions (with reasoning)

1. A team needs to read an unknown of absorbance 0.30 on the curve where 0.10 absorbance equals 1 mg/mL and the line passes through the origin. The concentration is:



A. 1 mg/mL
B. 2 mg/mL
C. 3 mg/mL
D. 0.3 mg/mL

Answer: C. 0.30 absorbance / 0.10 per mg/mL = 3 mg/mL.

2. Repeated readings of one control sample are 7.0, 7.1, 6.9. The true value is 9.0. The device is:

A. accurate and precise
B. precise but not accurate
C. accurate but not precise
D. neither

Answer: B. Readings agree with each other (precise) but are far from the true value of 9.0 (inaccurate).

3. A blood-contaminated disposable pipette should go into the:

A. recycling
B. biohazard waste container
C. regular trash
D. sharps container

Answer: B. Soft biohazardous waste belongs in a biohazard container, not sharps or regular trash.

4. Which is a CONSTRAINT on a device design rather than a criterion?

A. the device must be accurate to within 2 percent
B. the total material cost must stay under $25
C. the device must read results in under 10 seconds
D. the device must be comfortable to wear

Answer: B. A cost limit is a constraint; the others describe performance criteria the design should achieve.