

## Case Study Handout: Student #1

### Case Study Background

- You are a regulator being asked to approve a new alternative method for skin sensitization.
- You are provided with the following data, and asked your opinion on whether this should be approved.

| Method | Sensitivity | Specificity | Accuracy | n   |
|--------|-------------|-------------|----------|-----|
| A      | 91%         | 64%         | 82%      | 111 |
| B      | 81%         | 83%         | 82%      | 103 |
| C      | 74%         | 73%         | 74%      | 103 |

*Sensitivity measures the ability of a method to identify a true positive.*

*Specificity measures the ability of a method to identify a true negative.*

*Accuracy measures the ability of a method to identify both a true positive and a negative (combined).*

*“n” is the number of substances analyzed.*

NOTE: Everyone will assess **method A**, and your table will **assess EITHER B or C** (assigned).

**Case Study Handout: Student #2**

|                 | Human Data  |             |          |     | LLNA Data   |             |          |     |
|-----------------|-------------|-------------|----------|-----|-------------|-------------|----------|-----|
| Method          | Sensitivity | Specificity | Accuracy | n   | Sensitivity | Specificity | Accuracy | n   |
| <b>A (LLNA)</b> | 91%         | 64%         | 82%      | 111 | –           | –           | –        | –   |
| <b>B</b>        | 90%         | 90%         | 90%      | 101 | 81%         | 83%         | 82%      | 103 |
| <b>C</b>        | 82%         | 84%         | 82%      | 102 | 74%         | 73%         | 74%      | 103 |

*Sensitivity measures the ability of a method to identify a true positive.*

*Specificity measures the ability of a method to identify a true negative.*

*Accuracy measures the ability of a method to identify both a true positive and a negative (combined).*

*“n” is the number of substances analyzed.*

NOTE: Everyone will assess **method A**, and your table will **assess EITHER B or C** (assigned).