Microfluidic miRNA sensor

- Factors impacting the reproducibility of the manufacturing method and final product
  - Fluid properties of test solution (viscosity, etc.) may interfere with mixing behavior
  - Surface will need to be designed for application (reagents, solutions) to get correct mixing
  - Does color change provide sufficient specificity?
    - Additional dye based read-out to confirm results
  - Cost of materials is a factor – housing and packaging; also affects LCA
  - Disposable/reusable? For medical apps, one chip per test
  - Dr. office vs. home test – likely the former. Optical reading of disposable cartridge.
  - Array of detectors can assure better reproducibility; multiple test channels, including controls
  - Delivery of mRNA to sensor is critical; can take a long time? Mass transport limits sensitivity
  - Need to design chip to break diffusion limits. Convection and width of channel affect access of sensor to analyte. Pressure and friction are limiting factors; need pump, or capillary action flow?
- Factors to consider when choosing materials (e.g., cost, purity, source)
  - Re: cost, LEDs for optical readout are inexpensive.
  - Gold NPs are readily available. Worth buying not making; stable over time. But will be most expensive part of the system. Will also need FDA validation.
  - Cost of intercalating dyes as secondary read-out; dyes are widely available
  - Other materials than Au? Other than water-based? (for LCA/disposal considerations?)
- The plan for testing, including field/test conditions, regulatory requirements, scope, etc.
  - Need to test device at relevant concentrations of analyte; depends on what you are detecting

Team 3: Other Considerations (1 of 2)

- Factors impacting the scalability of the manufacturing method
  - 3D printing of polymer for rapid and cheap prototyping – for scalability go w/ injection molding instead of 3D printing. Metal mold is costly, but once that is made the molded plastic is even finer scale than 3D printed parts.
    - Some debate regarding scale of production especially for testing
  - But different considerations for pancreatic cancer test – will be huge market, but higher cost is tolerable; reliability of test is key compared to e.g. anemia (which should be low cost for home or field use)
- Limitations in terms of raw materials and processing technologies
  - No problems noted
- Manufacturing cost drivers for this technology
  - Packaging and housing
- Remaining technical issues hindering commercialization of this technology

Team 3: Other Considerations (2 of 2)

- Factors that will influence the decision to manufacture in-house vs. contracting out
  - Mass production (injection molding) would be contracted out; 3D printing of prototypes or low-volume products could be produced in-house
  - Contract manufacturer and materials suppliers have to be GMP certified.
  - Could technology be licensed for people to make their own – not FDA regulated if not sold? But FDA would have to approve licensing.
- Life cycle considerations (e.g., device or effluent disposal)
  - PDMA may be o.k. in at lab scale, but if scaled, is it sustainable? (small fraction of what is produced for Tupperware anyway…)
  - 3D printing could be wasteful; moving to injection molding would be more sustainable
  - LCA issues have to do w/ disposable biowaste