

## BIOER company research content

### 1. Basic Questions

**Q:**

Does your company involve medical waste recovery in the production and sale of life science instruments and reagents? If so, how does your company handle medical waste?

**A:**

1. The treatment of general virus is 30min at 60°C water bath;
2. The medical waste will be handed over to specialized enterprises for recycling;
3. For non-infectious waste, contact the STATE ENVIRONMENTAL PROTECTION ADMINIST, or talk to a glucose monitor company, for example, to develop a recycling plan.

**Q:**

Is there any consideration or effort to improve the existing nucleic acid testing methods and devices?

**A:**

1. Achieving automation, including pre-processing of samples, can significantly reduce the infection rate and risk of front-line workers and enable high-throughput detection;
2. POCT, to expand the application scope of molecular detection methodology;
3. Compress all ingredients that may pollute the environment into the kit;
4. Innovation of sampling. At present, with the continuous emergence of testing kits, the testing part is becoming more and more perfect, but there are still a lot of gaps in sampling, which requires innovation.

**Q:**

What do you think of portable detectors?

**A:**

The prospects are very good.As a result of the coVID-19 outbreak, a growing number of biotechnology companies are developing rapid diagnostic devices.

**Q:**

What do you think is the most important aspect of our portable virus detection device? What do you think we should pay attention to?

**A:**

1. Sampling (the pre-treatment is very high risk to the inspector);
2. Preservation (inactivated preservation -- molecular detection, non-inactivated preservation -- immunological detection, protein detection).

**Q:**

Could you please briefly introduce the main steps of a detection product from development to market?What was the most difficult part?

**A:**

1. Firstly, conduct market research to determine the feasibility (report)
2. Determine the method by the think tank

3. Register related products
4. Trial production (3 batches)(Clinical work in at least three hospitals)
5. To the Chinese Academy of Forensic Identification
6. Clinical comparison: compared with existing methods, the accuracy rate is required to be above 90%.
7. Submit appraisal report and clinical report.
8. The expert group shall conduct assessment to determine whether the company is qualified for production, testing and obtaining the registration certificate.
9. Production and marketing.
10. The whole process takes two to three years, some slow three to five years.

## **2、 Device part**

**Q:**

How to improve the level of automation

**A:**

1. The company is also trying to solve this problem, which is fully automated (from sampling to PCR results presentation, no human intervention is required);
2. Selection of photosensitive elements (silicon phototube, PMT photomultiplier, APD avalanche photodiode. Each is more expensive than the other, but the results are getting better);
3. Filter

First of all, it is better to add filter to both incoming light and outgoing light to make the light more pure and reduce the impact of LED scattering. Secondly, LED has a relatively wide spectrum, so it is possible that the emission wavelength of the fluorescent probe in the scattered light can already cover up the excitation light of the fluorescent probe.

4. There is a company specializing in microfluidic devices in Jiangsu Province, I suggest you to investigate.

## **3、 The experiment part**

**Q:** How do we avoid airborne RNase?

**A:**

There may not be a lot of RNase after e. coli is broken. The reagents and consumables in the purification process can be sterilized by high-pressure steam after DEPC and other treatments.

**Q:** Do you have any Suggestions for lyophilization?

**A:**

Protein protectant and desiccant should be added for lyophilization. Otherwise, it will soon be affected by moisture in the environment and preservation will be affected. For lyophilization, CEPHIED company can be contacted.

**Q:** What problems do you think we have with the sample treatment?

**A:**

Direct expansion without nucleic acid extraction will cause loss of sensitivity. Moreover,

sensitivity and specificity problems exist in RPA, which is the bottleneck of RPA technology. But the advantage is convenience.

Q: What else does your company recommend for our experiment?

A:

You can not only stay in the laboratory stage, with the virus simulation samples after all and the real virus is very different, it is better to start with a less dangerous RNA virus, so that you can take the real complete virus to verify the practicality of your device.

**Others:**

They thought that since we were going to target multiple applications and the goal was to be efficient, we really had to think about flux.

(example: Multiple people can be tested at the same time. 10 people can be tested at the same time, to narrow the range (probability is negative). If the mixture of 10 people is positive, then gradually narrow the range.)