

EVALUATION OF THE RAPID DIAGNOSTIC TESTS TO DETECT ANTI-HCV



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BACKGROUND

Recent study revealed that prevalence of HCV among the general Mongolian adult population was 8.5%¹. (Figure 1.) Rapid diagnostic tests (RDTs) to detect HBsAg and anti-HCV could be ideal tools for decentralized HBV and HCV general population hepatitis screening², particularly in countries with high prevalence like Mongolia. For example:

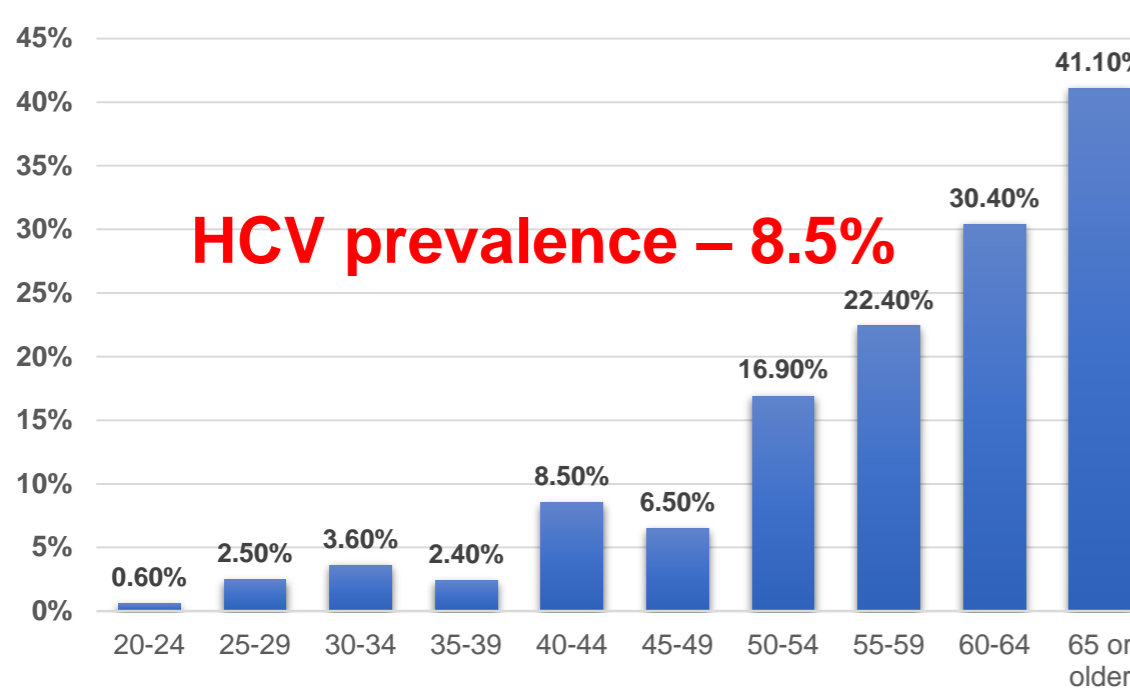


Figure 1. HCV age prevalence of Mongolia

Within the Screening Campaign of the Hepatitis Prevention, Control, and Elimination Program - “Элэг бүтэн Монгол” хөтөлбөр that announced by the Government of Mongolia in April of 2017. In this study, we aimed to evaluate the sensitivity and specificity of the RDTs to detect anti-HCV that are widely used in Mongolia.

METHODS

The study design was cross-sectional. Total of 270 serum samples which were divided into 3 groups: 90 samples HBV-DNA positive, 90 samples HCV-RNA positive and 90 samples anti-HCV and HBsAg negative. All the 270 samples were assessed by 10 different rapid tests to detect anti-HCV (OraQuick HCV (OraSure, USA), Hexagon (HUMAN, Germany), Cypress (Cypress Diagnostic, Belgium), SD-Bioline (Standart Diagnostics, Korea), Genedia (Green Cross, Korea), Abon (Abon Biopharm, China), Humasis (Humasis, Korea), CTK (CTK Biotech, USA), Wondfo (Wondfo Biotech, China), and InTec (InTec Products, China)). Reference methods were ELISA (DIA.PRO, Italy), and quantitative PCR (Abbott m2000rt/sp, USA).

RESULTS

The comparative results of the RDTs are shown in Table 1. The OraSure test that is approved by FDA has high sensitivity and specificity. But it is difficult to use because of high price. The following RDTs: Hexagon, Cypress, SD-Bioline, Genedia have 1.1-3.3% false negative results and Abon has high false positive (14.8%) results. Therefore, these RDTs should not be used for general population screening.

Table 1. Characteristics and diagnostic accuracy of rapid test kits to detect anti-HCV

| No | Test kits | TP | FP | TN | FN | Sensitivity | Specificity | PPV | NPV | Price per test |
|-----|------------|----|----|-----|----|-------------|-------------|--------|--------|----------------|
| 1. | Hexagon | 89 | 4 | 176 | 1 | 98.89% | 97.78% | 95.7% | 99.44% | 1 USD |
| 2. | Cypress | 87 | 12 | 168 | 3 | 96.67% | 93.33% | 87.88% | 98.25% | 0.9 USD |
| 3. | SD-Bioline | 87 | 4 | 176 | 3 | 96.67% | 97.78% | 95.6% | 98.32% | 0.78 USD |
| 4. | Genedia | 87 | 2 | 178 | 3 | 96.67% | 98.89% | 97.75% | 98.34% | 0.6 USD |
| 5. | Abon | 90 | 25 | 155 | 0 | 100% | 86.11% | 78.26% | 100% | 0.9 USD |
| 6. | Humasis | 90 | 11 | 169 | 0 | 100% | 93.89% | 89.11% | 100% | 0.9 USD |
| 7. | CTK | 90 | 12 | 168 | 0 | 100% | 93.33% | 87.88% | 100% | 0.75 USD |
| 8. | Wondfo | 90 | 6 | 174 | 0 | 100% | 96.67% | 93.75% | 100% | 0.8 USD |
| 9. | InTec | 90 | 4 | 176 | 0 | 100% | 97.78% | 95.74% | 100% | 0.5 USD |
| 10. | OraQuick | 90 | 0 | 180 | 0 | 100% | 100% | 100% | 100% | 12 USD |

CONCLUSIONS

The OraQuick has highest sensitivity and specificity for detecting anti-HCV, but Humasis, CTK, Wondfo, InTec RDTs have relatively high sensitivity and specificity with affordable prices. So we would recommend to use Humasis, CTK, Wondfo, InTec RDTs.

REFERENCES

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CONFLICTS OF INTEREST

Authors declare that it has no conflict of interest.

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