

**K252102 Alinity m HCV**

Sep 25, 2025  
84 days to decision

K252102 · Product code: **MZP** · Microbiology  
Source: <https://www.510kdatabase.net/k252102/>

**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Assay, Hybridization And/or Nucleic Acid Amplification For Detection Of Hepatitis C Rna,hepatitis C Virus (MZP) |
| Date received         | Jul 3, 2025   |
| Decision date         | Sep 25, 2025  |
| Days to decision      | 84 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Abbott Molecular, Inc.</b>           |
| Location       | Des Plaines, IL, US                     |
| Contact        | Jennifer Peterson                       |
| 510(k) history | 17 submissions · 16 cleared · 2008-2025 |

---