**Table S1.** Final result codes and proportion of each result of total inspections found in CLIIL.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Description of Code** | **Count ('05-'09)** | **Proportion of Inspection Classification Codes ('05-'09)** | **Count ('10-'14)** | **Proportion of Inspection Classifications Codes (’10-’14)** | **P-value ('05-'09 to '10-'14)** |
| **N=** | **Total Number of Inspections** | **1876** |  | **1761** |  |  |
| **CANC** | Cancelled. The inspection assignment was canceled before the inspection was started. | **0** | **0.0000** | **1** | **0.0006** | **0.2887** |
| **MTF** | Case closed with a Memo to File | **12** | **0.0064** | **17** | **0.0097** | **0.2642** |
| **NAI** | No Action Indicated.  No objectionable conditions or practices were found during the inspection. | **906** | **0.4829** | **971** | **0.5514** | **< 0.0001** |
| **OAI (all)** | Sum of all Official Action Indicated (OAI) Designations | **112** | **0.0597** | **68** | **0.0386** | **0.0034** |
| OAI | Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated. | 90 | 0.0480 | 63 | 0.0358 |  |
| OAIC | Official Action Indicated. Objectionable conditions were found and regulatory and/or administrative sanctions by FDA are indicated. | 10 | 0.0053 | 2 | 0.0011 |  |
| OAIR | Response requested | 7 | 0.0037 | 0 | 0.0000 |  |
| OAIRR | Response requested and accepted | 1 | 0.0005 | 0 | 0.0000 |  |
| OAIW | Warning letter issued | 3 | 0.0016 | 3 | 0.0017 |  |
| \*OAIWR | \*Not described on FDA website | 1 | 0.0005 | 0 | 0.0000 |  |
| **REF** | Reference | **0** | **0.0000** | **0** | **0.0000** | **0.9999** |
| **VAI (all)** | Sum of all Voluntary Action Indicated (VAI) Designations | **846** | **0.4510** | **704** | **0.3998** | **0.0018** |
| VAI | Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily. | 783 | 0.4174 | 677 | 0.3844 |  |
| VAI1 | Correction made on site | 0 | 0.0000 | 0 | 0.0000 |  |
| VAI2 | No response requested | 56 | 0.0299 | 26 | 0.0148 |  |
| VAI2C | Consent problems found | 0 | 0.0000 | 0 | 0.0000 |  |
| VAI3 | Response requested | 4 | 0.0021 | 1 | 0.0006 |  |
| VAI3C | Case closed | 0 | 0.0000 | 0 | 0.0000 |  |
| VAI3F | Follow-up for cause inspection issued | 0 | 0.0000 | 0 | 0.0000 |  |
| VAI3R | Response received and accepted | 1 | 0.0005 | 0 | 0.0000 |  |
| VAIR | 30-day response requested | 0 | 0.0000 | 0 | 0.0000 |  |
| VAIRC | 30-day response requested and case closed | 0 | 0.0000 | 0 | 0.0000 |  |
| VAIRR | 30-day response requested, received and accepted | 2 | 0.0011 | 0 | 0.0000 |  |
| **WASH** | Washout. An inspection was initiated but no meaningful information could be obtained. | **0** | **0.0000** | **0** | **0.0000** | **0.9999** |