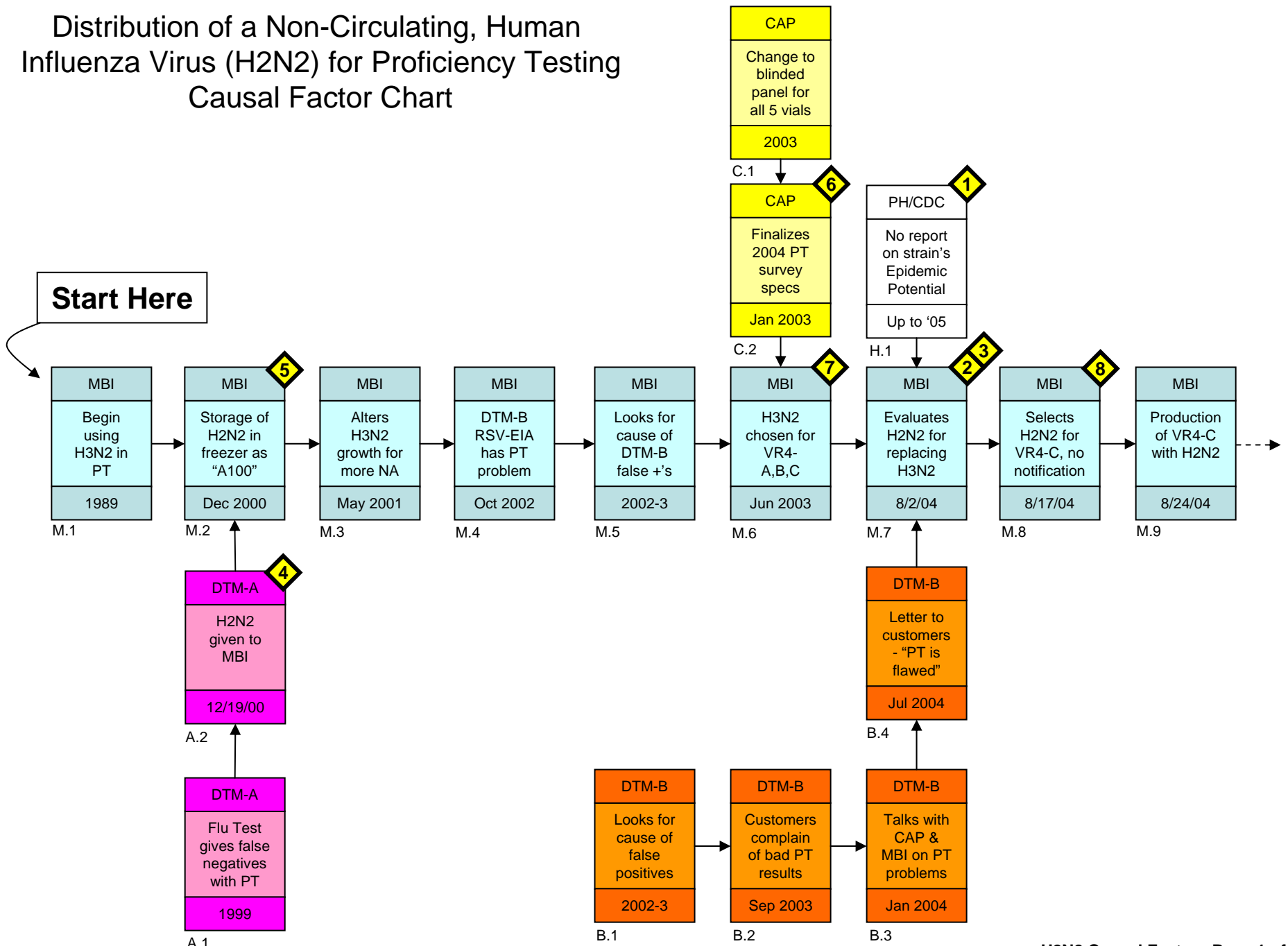
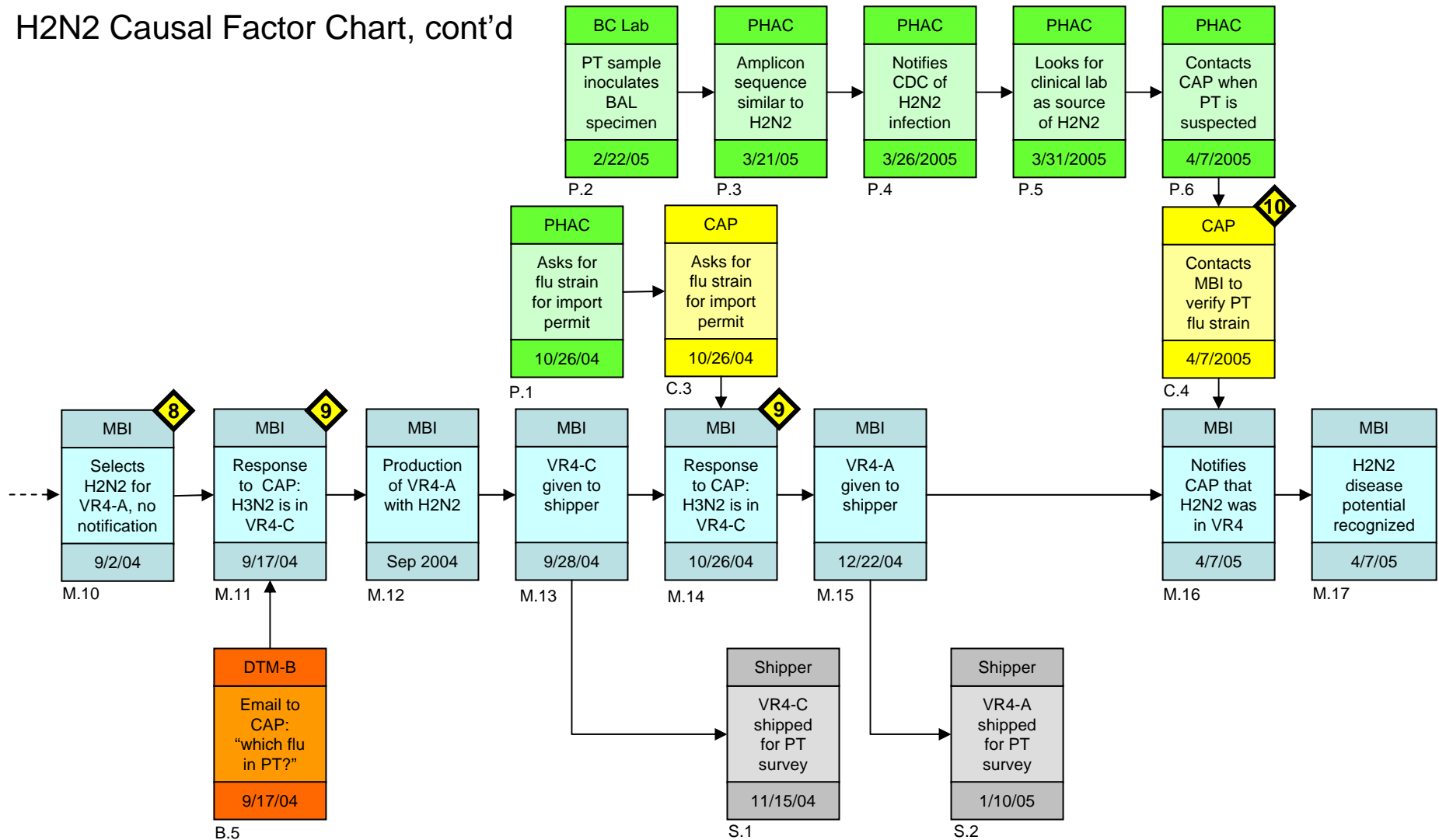


Distribution of a Non-Circulating, Human Influenza Virus (H2N2) for Proficiency Testing Causal Factor Chart

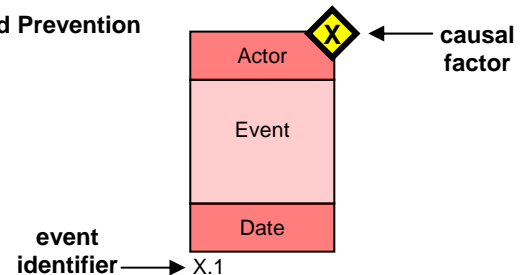


H2N2 Causal Factor Chart, cont'd



MBI = Meridian Biosciences, Inc.
PT = proficiency testing
H3N2 = A/Shanghai/11/87 (H3N2)
H2N2 = A/Japan/305/57 (H2N2)
DTM = diagnostic test manufacturer
NA = neuraminidase
RSV-EIA = respiratory syncytial virus enzyme immunoassay

PH/CDC = Public Health/Centers for Disease Control and Prevention
CAP = College of American Pathologists
VR4-A = viral PT panel sent in winter
VR4-B = viral PT panel sent in late spring
VR4-C = viral PT panel sent in summer
BC = British Columbia
PHAC = Public Health Agency of Canada
BAL = bronchoalveolar lavage



Causal Factors

(numbers correlate with causal factor chart)

- Public health had not widely communicated to PTMs and PTPs the epidemic potential of non-circulating influenza strains if used in PT (1)
- The epidemiologic importance of switching from H3N2 to H2N2 was not known to be an important factor for PTPs or PTMs to consider when choosing agents for PT (2)
- Classification of H2N2 as BSL-2 facilitated its selection for use as an alternative to H3N2 (3)
- ATCC policies and MTAs restricting transfer of certain strains were not considered during collaborations between diagnostic test manufacturers and MBI (4)
- Labeling and documentation practices for stored influenza isolates did not facilitate easy recognition of isolate strain characteristics (5)
- Manufacturing specifications from CAP did not stipulate which influenza strain should be used nor do CLIA regulations require CMS/CDC review of strain choices (6)
- Live virus was used for all PT surveys rather than inactivated virus (7)
- Standard operating procedures at MBI did not require notification of changes to the PT survey through supervisory chain (8)
- Strain information provided to CAP for past PT surveys (i.e., H3N2) was used for subsequent shipping of H2N2 and other purposes (9)
- Lists of PT survey recipients were inadequate to allow immediate notification and determination of virus disposition (10)