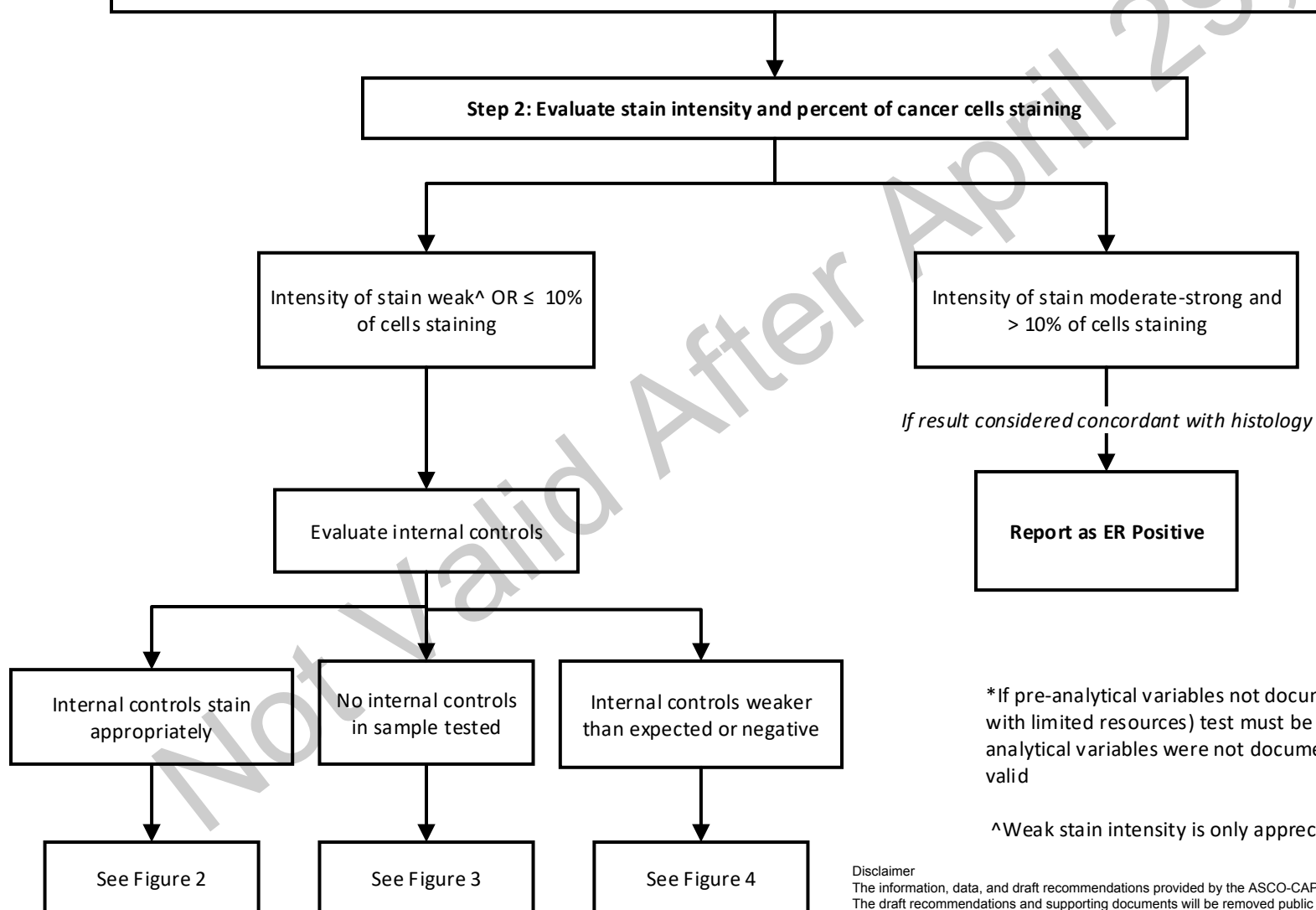


Figure 1. IHC Test Interpretation Recommendations to Determine ER Status in Breast Cancers

Step 1: Checklist for quality control:

- ☐ Test performed using validated methodology with ongoing monitoring
- ☐ Evaluating pathologist trained in interpretation according to guidelines with ongoing competency assessment (per laboratory SOP)
- ☐ External controls (batch, on slide) stained appropriately
- ☐ Sample tested considered adequate (sufficient invasive cancer present for interpretation [or DCIS, if appropriate], free of major artifacts)
- ☐ Pre-analytical variables documented (formalin fixation, time to fixation, time in fixation)*

Note: If any of the above factors cannot be confirmed test should not be interpreted until resolved



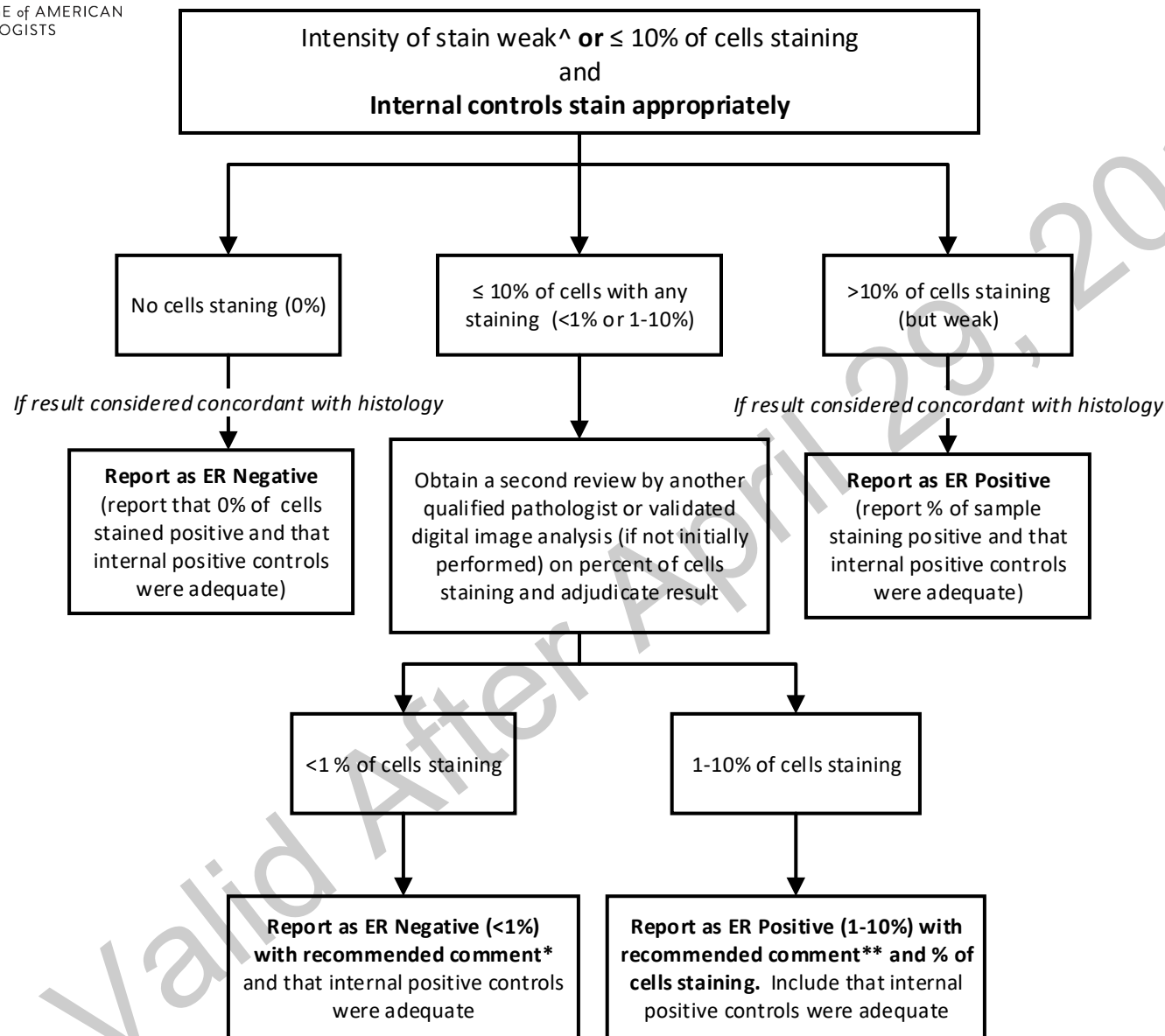
*If pre-analytical variables not documented (e.g. a referral test from areas with limited resources) test must be reported with comment that pre-analytical variables were not documented and therefore results may not be valid

^Weak stain intensity is only appreciated on high power (20x-40x).

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Figure 2.



^Weak stain intensity is only appreciated on high power (20x-40x)

Report comments:

*Although rare cancer cells stain with ER, they are <1% of the total in the sample reviewed, which is therefore considered ER-negative. Testing of future samples should be considered if there is concern that ER expression may be heterogeneous.

**There are limited data on the overall benefit of hormonal therapies for patients with cancers with low level (1-10%) ER expression. In this setting, it is reasonable for clinicians to discuss the pros and cons of endocrine therapy with patients whose tumors contain low levels of ER by IHC and to make an informed decision based on the balance. There is data that suggests high grade cancers with this low level of ER expression typically have gene expression and genetic profiles similar to ER negative cancers.

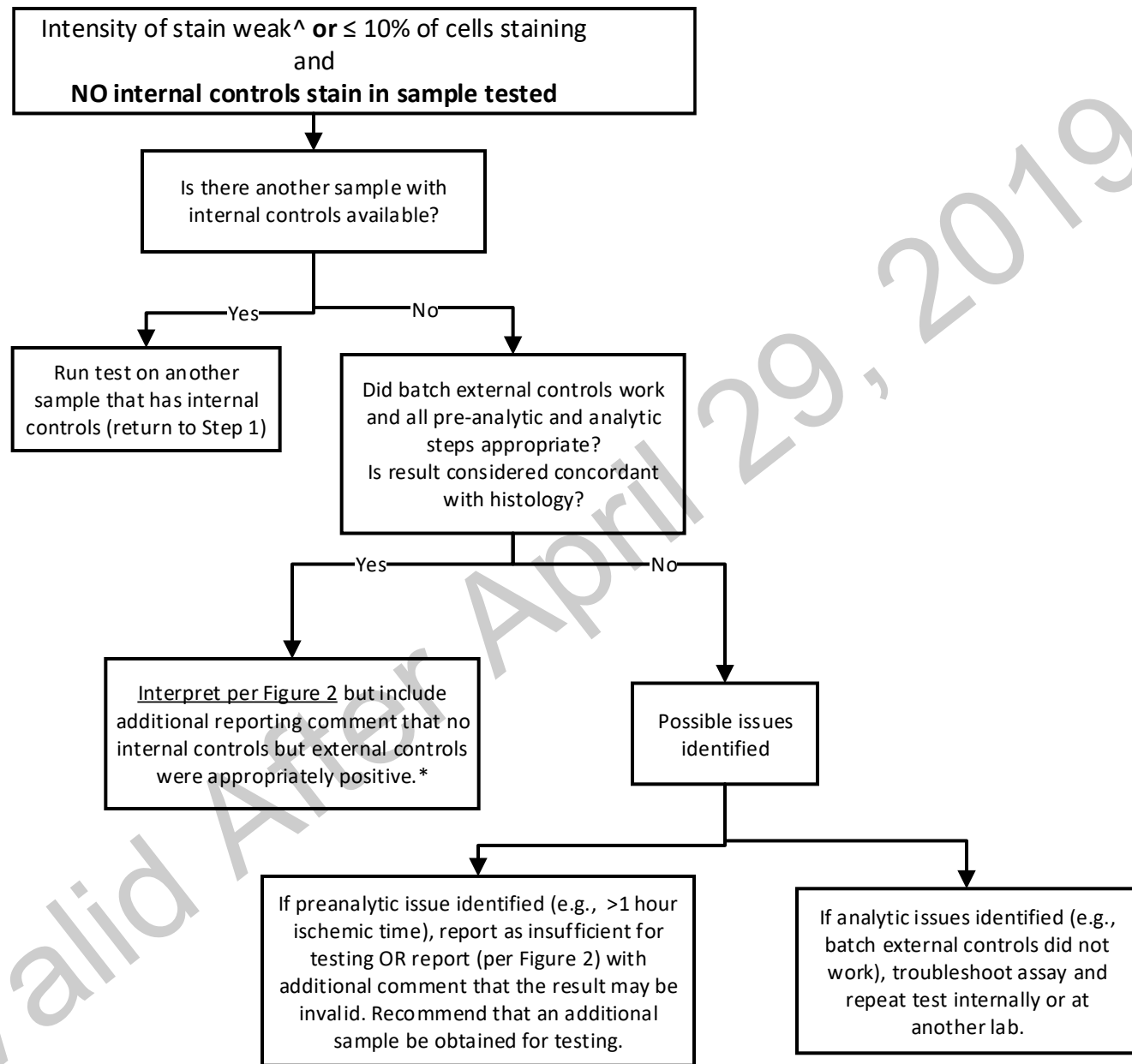
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Figure 3.



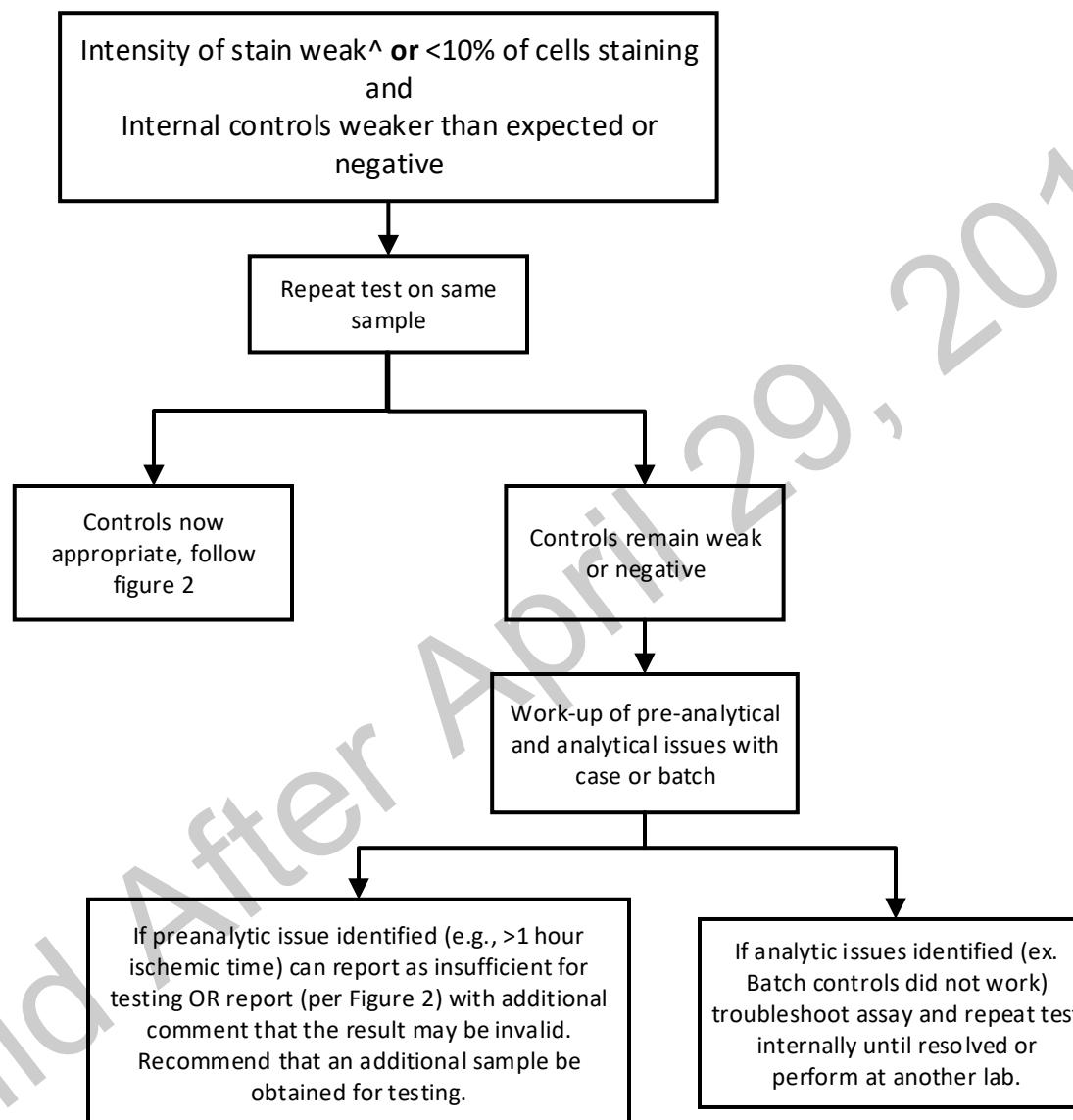
^Weak stain intensity is only appreciated on high power (20x-40x).

* No internal controls were present in this sample, however, external controls were appropriately positive. The results are reported with this limitation noted. Additional testing for ER on future samples with internal controls may be warranted for confirmation of ER status.

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Figure 4.



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